Diagnostic capabilities of the WHOQOL-100 Questionnaire in Life’s Quality assessment for patients with coronary heart disease and atrial fibrillation

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A- Conception and study design; B - Collection of data; C - Data analysis; D - Writing the paper; E- Review article; F - Approval of the final version of the article; G - Other (please specify)

ABSTRACT

Introduction: Circulatory system diseases have high medical and social significance, therefore, the study of the quality of life associated with health for cardiological patients is of great practical importance. A large number of methods for assessing the quality of life are known, but not all methods have a methodological justification in cardiology and practical approbation.

The aim of the work was to assess the clinical value of the WHOQOL-100 questionnaire for a group of patients with cardiovascular diseases.

Materials and methods: The work methodology is presented by the analysis of RISC, Springer Link, Oxford University Press, New England Medical Journal, British Medical Journal, Elsevier SCOPUS database, EBSCO platform, as a result, the WHOQOL-100 method was justified for use.

Results: It has been established that the psychological field (the ratio of positive and negative emotions) and the sphere of social relations with an emphasis on practical social support are components of the quality of life, which can be considered as key vectors of social rehabilitation and criteria for the social effectiveness of treating patients with cardiovascular diseases.

Conclusion: The international questionnaire WHOQOL-100 is recommended for use for cardiological patients with the subsequent analysis of the whole profile of quality of life.

Key words: Quality of life, medico-sociological study, diseases of the circulatory system, medico-social rehabilitation, effectiveness criteria.

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INTRODUCTION

The increase in life expectancy, the rapid development of medical science, qualitative and quantitative changes in the structure of morbidity, the widespread introduction of an individualized approach to each patient lead to the creation of a new paradigm of understanding the disease and the medical process in general from the standpoint of new approaches, in particular, from the standpoint of the Medical sociology. Today we are talking not just about “quality of life” (QL), but about a broader concept – about “health related quality of life”. QL assessment interest is reflected in the increase in the number of Russian and English-language articles on this topic.

In what cases can QL become a key goal of therapy? First, QL is important in the treatment of patients with chronic diseases (for example, cardiovascular diseases (CVD)). Secondly, QL is important if the patient has a disease with an unfavorable course and prognosis. Thirdly, QL is important for groups of diseases with subjectively severe symptoms when there is no danger to human life (for example, functional disorders of the cardiovascular system or the gastrointestinal tract).

Medico-social significance of (CVD) is not in doubt. According to the World Health Organization (WHO), 29% of the total number of deaths in the world is due to CVD, ½ of deaths are associated with coronary heart disease (CHD) (120-125 grades IX (CVD) in International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD 10). In official WHO bulletins, CHD is called a "pandemic of the 21st century" [1,2]. The emergence of persons suffering from CVD on disability is a serious problem. So, CVD are leading in the structure of causes of disability of the population of Russia for seventeen years (34.8-48.28%), and the proportion of persons who have become disabled due to CHD is the highest – 15.4% [3,4]. The leader among arrhythmias in prevalence is atrial fibrillation (AF) (ICD-10 code I48). It is proved that AF is the cause of every fifth stroke [5]. However, a high incidence of disability in CVD is associated not only with the clinical severity of the disease, but with a significant effect of the disease on the patient’s social environment (factors of social functioning and well-being, profession, presence / absence of social support, secondary socialization and re-socialization). International experience in treating CVD indicates that only by ensuring a high level of care for each patient at all levels - from the pre-hospital to the stage of medical and social rehabilitation – can a significant reduction in overall mortality due to CVD and increase in life expectancy in general [3,6].

In accordance with modern approaches to the rehabilitation of persons with CVD lifestyle changes and QL, which is determined by the level of somatic well-being when a person needs maximum re-socialization (preservation and/or restoration of social roles and status), acquire particular urgency. Thus, in case of CVD, after solving short-term tasks (stabilization of state), long-term tasks come to the fore where, along with maintaining a clinically stable state, prolongation of life and preservation/enhancement of the patient's QL are important. Unfortunately, at present, the medicalization of patients with CVD, without sufficient consideration of social factors and focus factors associated with QL, is characteristic of solving remote tasks. According to the recommendations for the treatment of CHD of the European Society of Cardiology, among the main tasks in the treatment of CHD, improving cardiac prognosis and QL are among the main issues [7,8]. The analysis is available for individual scientific publications on the assessment of QL in terms of social rehabilitation of patients with CVD.

The purpose of this study is to reveal the methodological approaches to the study of the quality of life and to demonstrate the possibilities of its application in cardiology by the example of substantiating the directions of medical and social rehabilitation and criteria for the social effectiveness of treating patients with AF and CHD.

MATERIALS AND METHODS

The goal was concretized in solving the following tasks:

1) to analyze bibliographic sources to understand the degree of elaboration of the problem and analyze the effectiveness of sociological tools that can be used to assess health-related QL;

2) to test the WHOQOL-100 questionnaire and show its high efficiency for the assessment of QL in CVD;

3) to select and form groups of cardiac patients (CHD, AF) and perform field case studies in clinical groups;

4) assess the health-related QL profile in relation to the underlying disease;

5) to determine the main characteristics of QL in the clinical and control groups, to conduct a statistical analysis.

6) to express the obtained results to substantiate the resocialization vectors of patients suffering from CHD and AF.

The study was carried out in two stages: theoretical and methodological and empirical.

At the first stage, the authors analyzed the current scientific medical literature on the problem over the past 10 years. The collection and analysis of materials was carried out in electronic libraries, articles of information resources were used: RISC, Springer Link, Oxford University Press, Elsevier SCOPUS database, EBSCO platform, The New England Journal of Medicine, The British Medical Journal. The search was carried out in a semi-automatic mode by the following keywords: quality of life, cardiovascular disease, social rehabilitation, cardiology, psychological support, resocialization. Next, combinations of the
above words were used. For the purpose of the study, all publications on the analysis of the quality of life in cardiology were used.

The empirical stage of the study was conducted at the following bases: the health care institution "Grodno Regional Clinical Cardiology Center", the health care facility "Grodno Regional Clinical Hospital of Medical Rehabilitation".

### Table 1. Characteristics of groups

<table>
<thead>
<tr>
<th>Group / gender</th>
<th>Men (N)</th>
<th>Women (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD (1 group)</td>
<td>37</td>
<td>34</td>
</tr>
<tr>
<td>AF(2nd group)</td>
<td>35</td>
<td>30</td>
</tr>
<tr>
<td>Healthy (3 group)</td>
<td>31</td>
<td>30</td>
</tr>
</tbody>
</table>

**Education (clinical group=136)**

<table>
<thead>
<tr>
<th></th>
<th>Secondary special</th>
<th>Highest</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>69</td>
<td>37</td>
</tr>
<tr>
<td>Children</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>(clinical group=136)</td>
<td>91</td>
<td>45</td>
</tr>
</tbody>
</table>

**Marital status (clinical group=136)**

<table>
<thead>
<tr>
<th></th>
<th>Unmarried</th>
<th>Divorced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married</td>
<td>80</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>39</td>
<td></td>
</tr>
</tbody>
</table>

**Education (control group=61)**

<table>
<thead>
<tr>
<th></th>
<th>Secondary special</th>
<th>Highest</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
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<td>15</td>
</tr>
<tr>
<td>Children</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>(control group=61)</td>
<td>43</td>
<td>18</td>
</tr>
</tbody>
</table>

**Marital status (control group=61)**

<table>
<thead>
<tr>
<th></th>
<th>Unmarried</th>
<th>Divorced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Married</td>
<td>32</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>19</td>
<td></td>
</tr>
</tbody>
</table>

**Object:**

Patients with CVD (CHD, AF) aged 40 to 65 years who are hospitalized and control group.

**Subject**

Features of QL in patients with CVD (CHD, AF).

**Inclusion Criteria**

1. Diagnoses of AF or CHD.
2. The ability to obtain additional information about the patient (socio-demographic, anamnestic, etc.).
3. The presence of the informed consent of the patient to participate in the study.

**Exclusion criteria**

Acute or subacute forms of coronary artery disease, congestive heart failure, severe extracardiac pathology, myocardial infarction history of less than 6 months, the patient is over 65 years of age. The clinical group consisted of 136 patients, the control group – 61 people with a normal rhythm, without complaints, signs of CVD and dispensary observation on the studied diseases. The groups are comparable by sex ($\chi^2 = 0.17$, $p>0.9$), age ($\chi^2 = 4.19$, $p>0.1$). All patients and individuals in the control group received voluntary informed consent to participate in the study. Patients were selected only in two centers, the volume of the control group can be explained solely by the authors' desire to achieve compliance with the clinical group and to achieve the lack of statistical differences by gender and age. Also, the number of patients in the control group was limited by the timing and amount of funding.

The design of the empirical part of the work: a controlled, single-step open-source clinical trial.

The Microsoft Excel 2010 program was used to process and present the results of the study. The results of the clinical study were processed using the STATA10 software package. The methods of non-parametric statistics are applied. Non-parametric Chi-square ($\sigma^2$) criteria with Yates correction (with a small number of samples) and the Kruskal-Wallis criterion.
were used. The result was assessed as statistically significant at a significance level of $p < 0.05$. When pairwise comparison of groups used the criterion of Mann-Whitney with the amendment of Bonferoni.

**RESULTS**

Based on a analysis of literary sources, it has been established that to date, more than 1,000 tools have been proposed for evaluating QL, and the most well-known ProQolid database includes about 700 descriptions [8]. The distribution of methodological approaches to evaluating QL can be described as follows: 22% are general methods, 18% are applicable for diagnosing specific aspects of QL, 46% are narrowly specific for a particular disease or group of people, 10% are related to the economic rationale for various investments of resources for improving QL, 1% – individualized methods and surveys [9]. Most methods for diagnosing and evaluating QL are used intuitively spontaneously, without regard to patient-dependent factors (language, culture, education, etc.). There are several non-specific questionnaires that are most actively used to assess health-related QL, for example, the Quality of Life European Quality Assessment Questionnaire (EUROQOL) or the Concise Health Assessment Form (MOS-SF 36), the Nottingham Health Profile (also Nottingham Health Profile), Quality of Life Index and others [6,7,8]. The major drawbacks of the above-mentioned questionnaires are: the lack of an adapted Russian-language version, a non-methodological approach, in some cases, the complexity and complexity of integration with other diagnostic methods and the results of the survey (statistical inconsistency and the impossibility of conducting correlation comparisons and analysis), etc.

Comparative analysis of the main components-subspheres of QL of patients with CVD revealed significant differences with the control group, as well as within the clinical group between patients with AF and patients with CHD, which is reflected in Table 2.

<table>
<thead>
<tr>
<th>№</th>
<th>QL domain/group</th>
<th>CHD (1 group)</th>
<th>AF (2nd group)</th>
<th>Healthy (3 group)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Men</td>
<td>Women</td>
<td>Men</td>
</tr>
<tr>
<td>1.</td>
<td>Domain I Physical*</td>
<td>12.08</td>
<td>11.01</td>
<td>10.36</td>
</tr>
<tr>
<td>3.</td>
<td>Domain III Level of Independence**</td>
<td>11.06</td>
<td>11.05</td>
<td>10.03</td>
</tr>
<tr>
<td>4.</td>
<td>Domain IV Social Relationships*</td>
<td>11.3</td>
<td>11.5</td>
<td>10.6</td>
</tr>
<tr>
<td>5.</td>
<td>Domain V Environment</td>
<td>14.01</td>
<td>13.51</td>
<td>14.00</td>
</tr>
<tr>
<td>7.</td>
<td>QL INDEX</td>
<td>74.74</td>
<td>71.59</td>
<td>70.6</td>
</tr>
</tbody>
</table>

Note. * – differences between clinical groups and the control group ($p < 0.05$),
** – differences between clinical groups and control group ($p < 0.01$)

A detailed analysis of the QL profiles in the experimental groups revealed that the following areas of QL were statistically significantly impaired in both AF and CHD: physical, psychological, and social relations ($p < 0.05$).

When paired comparison of the indicator of QL within clinical groups (Kruskal-Wallis criterion), it was found that a statistically significant decrease in QL in CHD is observed as the functional class increases, which is logical to explain the emerging limitations of habitual life activity ($p < 0.01$), but due to the small the number of observations within the group with CHD this conclusion needs to be checked.

Patients of both clinical groups who had jobs, or even worked in retirement, evaluated QL better, including the level of independence, social relations and the spiritual sphere ($r = 0.54, p < 0.05$). Patients who did not work at the time of diagnosis (pension, disability) were significantly lower rated as total QL ($r = 0.74, p < 0.01$), and virtually all of its individual sub sphere ($r = 0.65, p < 0.05$). When conducting a correlation analysis, there were no significant differences in the assessment of QL depending on the duration of the disease in CHD and AF.

**DISCUSSION**

The modern concept of assessing and studying health-related QL includes three components [10].

1. Multidimensionality. In assessing QL related to health, the parameters, both associated and non-associated with the underlying disease, are used, which allows us to accurately differentiate
Female patients of the 1st clinical group evaluated their lower QL (by selective subsphere) compared with men of the same group suffering from coronary artery disease. At the same time, when comparing the three groups (CHD, AF and healthy) among female patients, it was found that patients from the 1st group presented the most active complaints of pain, fatigue, discomfort, decreased vitality, fatigue during the day, than individuals with AF (clinical group 2, (p <0.001)). It is important that not the cardiac pain itself was perceived by women as an obstacle to a full life, but the fear of its occurrence (p <0.05). The indicators of the “Physical Sphere” in women suffering from CHD decreased to a greater extent due to such sub spheres as F 1 Pain and discomfort, F 2 Energy and fatigue. In women with AF, the value in the “Physical Sphere” was reduced, with a significant difference due to the F 2 Energy and fatigue. Similar results for the indicator “Physical Sphere” were obtained by Russian authors Baleva et al. [1], who studied QL patterns in patients with CHD [1].

The “level of independence” in all three groups was assessed by respondents as medium, the lowest values were found for F 11 Dependence on medication or treatments (p <0.01), in patients with CHD, the changes in sub sphere F 10 Activities of daily living were statistically significant (p <0.01). A low level of satisfaction of patients of both clinical groups in the F 19 Health and social care: accessibility and quality was identified. Persons in the control group had significantly higher rates for this sub sphere (p <0.01), which can be explained by the less need to seek medical help.

When analyzing the components of the “Psychological Sphere”, it was found that in both clinical groups the values for the subsphere F4 Positive emotions were reduced, and increased for F8 Negative emotions (p <0.05). A characteristic pattern of QL of patients with CHD was the reduction in the total value of the “Social Relations” sphere (p <0.05), which describes the possibility of forming constructive personal relationships, the ability to take any real support of the people around them, their practical participation in life, and the ability to provide such same support to others. The index of the sub-sphere “Sexual activity” in all patients with CVD was assessed as average. Perhaps the limitations in this area were associated with the expectation of side effects of drug treatment, the availability of available information on the associated effects of drugs for the treatment of coronary heart disease and AF. Component QL – “Spiritual sphere” in patients with CVD in both clinical groups and in the healthy group has no statistically significant differences. This suggests that personal views and worldview largely provide a person with a sense of well-being, help to cope with changes in the personality, and in social relationships that occur as a result of chronic illness. Thus, it is the maintenance and development of the spiritual sphere that can be considered as an essential resource of compensation for

and highlight the degree of influence of the disease on the patient’s condition.

2. Temporal variability. Health related quality of life changes over time and depends on the patient’s condition. Information about QL allows you to monitor the patient's condition and, if necessary, adjust the treatment.

3. Direct participation of a person in the assessment of his condition. This component is the most important. So, it is not a reliable assessment of the patient's QL conducted by relatives or medical staff. Representatives of the patient’s family are characterized by “guardianship syndrome”, which means a hypertrophied assessment of the severity of the condition. And medical workers tend to evaluate the patient’s QL higher than the patient himself, which is described in the literature under the term “benefactor's syndrome” [11]. Thus, the main way to assess QL is solely the opinion of a particular patient.

Approaches to the study of QL in various diseases vary depending on the time intervals for evaluation: they distinguish the immediate and long-term indicators of QL. The analysis of the nearest characteristics is associated to a greater extent with the description of the patient’s subjective sensations (as a rule, the nearest indicators of QL are associated with a short-term decrease in QL: symptoms of the disease, complaints, temporary disability). Evaluation of the long-term characteristics of QL is much more complex and depends on a large number of patient-dependent (significant reduction in social adaptation, dependence on the use of drugs, compliance with the doctor's recommendations, compliant behavior) and patient-dependent factors (clinical features of the disease, permanent disability, lack of a rehabilitation system, etc.).

An analysis of the available tools for assessing the quality of life led to the conclusion that the most acceptable method for assessing QOL is the international questionnaire WHOQOL-100. The WHOQOL -100 questionnaire is a kind of measure of the welfare of the subjects and their satisfaction with their lives. For the objectification of the quality of life index, it used a testological approach borrowed from psychology and received further development and wide distribution in medicine.

Why WHOQOL -100? WHOQOL -100 is universal, which makes it possible to conduct cross-cultural comparisons, the questionnaire was created by an international commission of experts of different specialties, and was simultaneously validated in 15 research centers of the world, with different levels of economic development. The result of the diagnosis is a full profile QL.

In connection with the above, we chose exactly the questionnaire WHOQOL-100 for solving empirical problems.
CONCLUSIONS

We found that the components of quality of life, which can be considered as key vectors and, accordingly, indicators of the effectiveness of social rehabilitation of patients with circulatory system diseases, are: psychological sphere (correlation of positive and negative emotions) and social relations with an emphasis on practical social support. The indicator of QL of persons with CVD is an independent multifactorial parameter of the physical condition and the efficiency of patient re-socialization. The patient's QL verification in clinical practice will complement the objective picture of the disease.

Conflicts of interest
None.

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REFERENCES


