

Use of research methods in the process of pulmonary rehabilitation and physical therapy of persons with chronic obstructive pulmonary disease (review of clinical guidelines)

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To date, the analysis of research methods and indicators on the basis of which the assessment of important areas of the physical, functional and psychoemotional state of patients with chronic obstructive pulmonary disease (COPD) at different stages of physical therapy is relevant.

Purpose: *to analyze and systematize recommendations on the use of research methods in the process of pulmonary rehabilitation and physical therapy in chronic obstructive pulmonary disease.*

Material & Methods: *the available clinical guidelines for the diagnosis, treatment and pulmonary rehabilitation of patients with COPD are available. 13 clinical guidelines were analyzed.*

Results: *selected research guidelines and categories were evaluated in selected clinical guidelines: diagnostic criteria, criteria for participation of patients in the pulmonary rehabilitation program, prognostic criteria, and selection criteria for pulmonary rehabilitation and physical therapy strategies, effectiveness markers. In clinical guidelines, the methods of research that recommend the evaluation of patients with COPD in the treatment and recovery process are grouped as follows: research methods and indicators of the functional state of the respiratory and cardiovascular system, estimates of the level of dyspnea, quality of life and the manifestation of COPD symptoms, the level of physical performance and integrated performance.*

Conclusion: *most recommendations on the use of methods for studying patients with COPD are justified for diagnosis, prediction and selection of the strategy of drug treatment and oxygen therapy. Most of the recommendations are not sufficiently focused on using research methods and indicators as prognostic criteria and markers of the current and long-term effectiveness of physical therapy. Groups of research methods and indicators have been identified, with the help of which it is recommended to evaluate patients with COPD at the stages of diagnosis, patient selection, predicting the course of the disease, choosing a strategy of the pulmonary rehabilitation program and evaluating its effectiveness.*

Keywords: *chronic obstructive pulmonary disease, COPD, pulmonary rehabilitation, physical therapy, clinical setting.*

Introduction

Chronic obstructive pulmonary disease (COPD) has been on the list of priority diseases in the health care system of Ukraine [1] and the world [18] for more than a year. Pulmonary rehabilitation (PR) with its mandatory component of physical therapy (PT) is recommended for patients with COPD at all stages of treatment [19].

In PT, it is customary and necessary to control the initial, current and final state of the patient, due to which results are predicted, the selection and dosage of the means of PT, the assessment of their effectiveness and the correction of interventions. Accordingly, the research methods used by the physical therapist when working with patients with COPD should be informative, reproducible, easy to perform, correlate with the patient's quality of life, symptoms and clinical course of the disease.

Today, the analysis of research methods and indicators, on the basis of which the important areas of the physical, functional and psycho-emotional state of patients with COPD are evaluated at different stages of PT, is relevant.

Relationship of research with scientific programs,

plans, themes. The work is carried out in accordance with the theme of the Master Plan of the research work of the Lviv State University of Physical Culture for 2016–2020. "Theoretical and methodological foundations for the physical rehabilitation of persons with disabilities with disorders of the musculoskeletal system and respiratory system" (Minute No. 8 dated 04.19.2016).

Purpose of the study: to analyze and systematize recommendations on the use of research methods in the process of pulmonary rehabilitation and physical therapy in chronic obstructive pulmonary disease.

Material and Methods of the research

A review of available clinical guidelines and protocols for diagnosis, treatment, management and pulmonary rehabilitation of patients with COPD has been conducted. The search was carried out in the scientific evidence database PubMed and PEDro. Analyzed available publications as of November 13, 2017 (Table 1).

Search criteria are the keywords "Chronic obstructive pulmonary disease". In PubMed, the search was limited to publications for the last 5 years on installations (guideline) for treat-

ment and management, pulmonary rehabilitation and physical therapy for patients with COPD.

Table 1
Quantitative results of the search for publications

Publications database	Search words	Found / Added to analysis
PubMed	«Chronic obstructive pulmonary disease guideline» Search for the last 5 years	572 / 12
PEDro	«Chronic obstructive pulmonary disease»	17 / 9

The study, added to the review, met the following criteria: chronic obstructive pulmonary disease, a review, recommendations or practical instructions from the general principles of treatment, pulmonary rehabilitation or PT in COPD.

Seized: systematic examinations; abstracts of conferences; articles that are not available in full; textbooks; clinical trial protocols have been registered; national adaptation of the recommendations of the World Health Organization (WHO) GOLD (Global Initiative for Chronic Obstructive Lung Disease).

In addition, the publications were withdrawn, did not contain general recommendations on the treatment, management, rehabilitation and physical therapy of patients with COPD. Not taken into account the publication on surgical intervention study of the influence of drugs and medical interventions; research of other pathologies in combination with COPD; the study of structural, functional changes in COPD.

Results of the research

Analyzing the available clinical guidelines (including the PR Protocols), we were looking for answers to the following questions:

- what indicators and research methods can be criteria for patient participation in the program of PR, the appointment of a specific program or funds PT;
- which indicators can be prognostic criteria that can be used to predict the effectiveness of PT;
- what indicators can be markers of effectiveness of application of PT;
- with the help of which indicators it is possible to estimate the necessity of correction of physiotherapeutic intervention.

13 clinical guidelines (minutes) were analyzed, among them the Order of the Ministry of Health of Ukraine No. 555 (dated June 27, 2013). "Chronic obstructive pulmonary disease: Adapted clinical setting based on evidence" [2].

Categories of indicators and research methods that are evaluated in the recommendations of clinical guidelines (Table 2):

1. Diagnostic criteria – the most important clinical signs and/or laboratory data, on the basis of which a reasonable diagnostic conclusion about a disease can be made. In addition, this group included research methods and indicators to determine the stage, the severity of COPD, the level of symptoms at the diagnostic stage.

2. Criteria for the participation of patients in the PR and PT program – indicators that are recommended to be considered for referring a patient to participate in the PR and PT program.

3. Prognostic criteria are indicators or a group of indicators that provide an opportunity to predict the effect of PR and PT, the duration of pulmonary rehabilitation and physical therapy, the level of restoration of the function of external respiration, physical working capacity and the growth of the quality of life of the patient with COPD.

4. Criteria for choosing the strategy of PR and PT – research methods and indicators, which allow to objectively choose one or another strategy or program of PR and PT.

5. Effective markers – indicators that may indicate changes in the functional state of a person are sensitive to physiotherapeutic intervention and correlate with clinically relevant indicators of the state of external respiration, COPD symptoms, physical working capacity, level of functioning and quality of life. Effective markers are indicators that allow us to assess the impact of the program of physical therapy as a whole, each individual session, and even an individual intervention, is applied.

In the analyzed clinical guidelines, the most prominent are the diagnostic criteria for COPD, with different details given in ten of 13 sources (see Table 2). The main method of research in this category is spirometry, which is indicated in all 13 installations, and in three of them – as the only diagnostic method [3; 7, 14]. Since there is only a weak correlation between the spirometry index – the forced expiratory volume in the first second of expiration (FEV_1), symptoms, and impairment of the patient's health, it is necessary to symptomatically evaluate [10; 11]. In this regard, along with spirometry, it is recommended to use instruments at the diagnostic stage to determine the degree of symptoms of the disease (CAT, CCQ ©), dyspnea (mMRC), quality of life (SGRQ) [17] and physical performance [12; 21]. According to the clinical setting [22], the estimates of spirometry, symptoms of dyspnea and symptoms (mMRC, CAT) allow the patient to be assigned to one of the three groups for which drug therapy algorithms are developed. According to GOLD-2017 [8], the results of spirometry, recording of exacerbations (including hospitalization) and mMRC and CAT indicators are taken into account for the distribution of patients into four clinical groups (A, B, C, D). It allows individualization of therapy.

The protocol for the treatment of COPD [13] recommends the use of spirometry, in particular, the FEV_1/FVC indicator for diagnostic purposes. In this clinical setting, there are no recommendations to apply other quantitative assessments of the manifestation of symptoms during a certain time, however, in the discussion and justification of the protocol it is indicated that mMRC and CAT questionnaires may be useful. Systematic tracking of changes using these questionnaires can help identify the development of concomitant comorbid conditions in the early stages and identify patients who are recommended for a pulmonary rehabilitation program.

In the H. Kankaanranta protocol (H. Kankaanranta, in 2015) [12], great attention is paid to the diagnosis of COPD and the assessment of the clinical severity of the disease, and later becomes the basis for choosing a specific treatment regimen. When di-

Table 2

Research methods and indicators by which it is recommended to evaluate patients with COPD

Protocols, year	Categories of indicators				
	diagnostic criteria	criteria for participation in the program of PR and PT	prognostic criteria	criteria for selecting a strategy for PR and PT	effectiveness markers
Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017 [8]	Spirometry, mMRC, CAT, CCQ®	–	Spirometry, mMRC, CAT, CCQ®	Spirometry, mMRC, CAT	Spirometry, CAT, CCQ®
Ian Yang, 2017 [21]	Spirometry (FEV ₁ /FVC), mMRC, CAT, 6MWD, shuttle walk test	–	–	–	Spirometry, 6MWD, shuttle walk test, SpO ₂
H. Kankaanranta, 2015 [12]	Spirometry (FEV ₁ /FVC), CAT, mMRC, 6MWT	–	–	–	–
Hyoung Kyu Yoon, 2014 [22]	Spirometry, mMRC, CAT	–	–	–	–
2014 [13]	Spirometry (FEV ₁ /FVC)	–	–	–	–
Maria Rosa Gell Rous 2014 [9]	–	mMRC	–	SpO ₂	mMRC, initial and dynamic indices of dyspnea, oxygen cost diagram, CRQ, Borg scale, SGRQ, questionnaire SF36 or SF12, CAT
Blair Anderson 2013 [3]	Spirometry	–	–	–	–
C. E. Bolton, 2013 [4]	–	–	Charlson index	HADS, MRC	–
E. W. Russi 2013 [17]	Spirometry (FEV ₁ , FEV ₁ /FVC), mMRC, CAT, SGRQ	–	Spirometry, BODE index	–	–
A. Qaseem 2011 [14]	Spirometry	Spirometry	–	–	–
M. Rudolf 2010 [7]	Spirometry	MRC	BODE index	SpO ₂	–
Davoren A. Chick 2010 [6]	Spirometry (FEV ₁ , FEV ₁ /FVC)	–	BODE index	–	–
Andrew L. Ries 2007 [15]	–	–	–	–	quality of life assessment

Remark:

CAT – COPD Assessment Test;

CCQ – COPD Control Questionnaire;

MRC – Medical Research Council Questionnaire;

mMRC – Modified British Medical Research Council Questionnaire;

SGRQ – questionnaire hospital of St. George for the assessment of respiratory function;

HADS – hospital anxiety and depression scale;

6MWT – 6 minute walk test;

6MWD – distance traveled when performing 6MWT;

ECG – electrocardiography;

BODE index – integral index containing FEV₁, 6MWD, mMRC, body mass index;

SpO₂ – oxygen saturation in peripheral blood;

SF36 or **SF12** – non-specific questionnaires for assessing the quality of life, complete (SF36) and abbreviated (SF12) versions;

FEV₁ – forced expiratory volume in the first second of expiration (FEV₁);

FEV₁/FVC – the ratio of volume of forced exhalation for the first second (FEV₁) to the indicator of forced vital capacity of the lungs (VC).

agnosing COPD, spirometry is recommended with a test for bronchodilation. This criterion is also associated with the risk of mortality. The level of symptoms and quality of life was proposed to be assessed using the CAT® and mMRC questionnaires. Another diagnostic criterion for assessing the ability to withstand physical activity is the 6-minute walk test. (6MWT).

Patient participation criteria in the PR program are the least

described. On the one hand, this may be due to the fact that the PR program is recommended to offer all stable patients with dyspnea, which limits physical activity despite medical treatment, and patients who were hospitalized due to exacerbation [13; 14; 15]. Accordingly, if there are no contraindications or cautions to PR and PT [7], then patients with COPD are encouraged to participate in the pulmonary rehabilitation

program. According to scientists (A. Qaseem 2011) [14], it is recommended that PR should be prescribed to patients with FEV_1 ($FEV_{1\%}$), less than 50% of their due. At the same time, clinicians consider it necessary for PR for patients who have manifestations of COPD and restrictions on performing exercises with FEV_1 exceeding 50% [14].

So, M. Rudolf (M. Rudolf 2010) [7] indicates that PR should be offered to all patients with COPD who consider themselves functionally limited, which usually corresponds to shortness of breath with a score of 3 points and above MRC questionnaire. It is noted that the HR program is not suitable for patients who cannot walk, have unstable angina, or have recently suffered a myocardial infarction. In particular, Maria Rosa (Maria Rosa Gyll Rous, in 2014) [9] notes that patients should be carefully selected for participation in the HR program. Candidates for participation in the PR program are patients with COPD with dyspnea with a score of 2 or higher mMRC (level 1A). In addition, for the initial assessment of candidates for PR specialists of the multidisciplinary team are encouraged to conduct a study. In particular, the pulmonologist should conduct an initial clinical, radiological and functional assessment of the patient. The use of physical therapy involves a preliminary electrocardiography, 6-minute walk test, a test with a maximum load (shuttle walk test or bicycle ergometry) [9].

Predictive criteria were specified in five protocols. As a prognostic criterion in the installation [4], it is recommended to use the Charlson Comorbidity index (comorbidity index). The Charlson Comorbidity Index was developed and approved as an indicator of the risk of mortality up to one year and the severity of the disease [16]. This indicator, which takes into account the influence of comorbidities [5], does not in any way predict the possible results of PT. Thus, this indicator can be used by a physical therapist in his practice to assess the severity of the disease and predict the patient's mortality, but not as a prognostic criterion for the effectiveness of PR or PT.

If earlier it was believed that the main manifestation of COPD is dyspnea and evaluating its manifestations using mMRC is sufficient to predict the future risk of mortality, then already in GOLD-2017 [8] for this it is recommended to further evaluate the manifestation of symptoms of the disease using methods such as CAT and CCQ® According to the account of these indicators in the classification scheme of separation of patients in the "ABCD" group is important not only for diagnosis, but also for prediction [8].

In the installations of M. Rudolf [7] and Davoren A. Chick (Davoren A. Chick 2010) [6], it is recommended to consider the integral index BODE (contains body mass index, FEV_1 , mMRC and 6MWD results) as a prognostic factor.

When choosing the strategy of the PR and PT programs, it is recommended to consider the results of the assessment of the level of anxiety and depression (HADS) [4], dyspnea (MRC) [4; 8] and level of education (knowledge of the disease) [15], spirometry and manifestation of disease symptoms (CAT) [8]. The recommendations mainly concern the introduction of certain corrective elements (for example, psychological support, educational components) into the PR programs. Pulse oximetry is used to estimate the need for the use of supplemental oxygen [7; 9]. In particular, patients in whom SpO_2 decreases to 90% or less, can benefit from supplemental oxygen during a session of exercise. Accordingly,

the results of pulse oximetry are recommended for determining the need for oxygen therapy [7].

In the clinical setting [4], the results of the mMRC questionnaire are suggested to be taken into account in choosing the type of PR. In particular, patients who are functionally limited to shortness of breath with a score of 2 points on the MRC questionnaire are recommended to be referred for participation in the LR program (Evidence Class D). Patients score 3–5, which are functionally limited to shortness of breath, should be attributed to the ambulatory version of PR. Patients with an MRC score of 5 points do not leave the home, do not offer routine control and PR out of the home (grade B) [4]. In this clinical setting, it is recommended to evaluate the level of anxiety and depression in the HADS questionnaire. It was found that the use of PR leads to a significant reduction in anxiety and depression in those patients who had "obvious" or "probable" anxiety or depression at an initial stage [20]. According to this indicator for the PR, it is possible to identify patients who need to be referred for support and management of depression to a psychologist [4].

According to the practical installation [15], education of patients with COPD should be an integral component of pulmonary rehabilitation. Accordingly, when a patient is not well informed about his condition, the educational component in the Republic of Latvia becomes mandatory and should contain information about self-control, prevention and treatment of exacerbations.

In the protocol GOLD-2017 [8], it is proposed by spirometry, mMRC and CAT to assign a patient to a specific group according to the classification scheme, which can facilitate the selection of individual treatment methods.

Markers of effectiveness of PR and PT. In the practical setting [15], a number of studies have been conducted on the dynamics of the quality of life indicator over a period of 10 days to two years after the use of PR. It is indicated on the improvement of the quality of life index (QL) after the application of the PR program from 4 weeks to 6 months. It is noted that, unlike other indicators, a high level of quality of life in comparison with control groups is maintained (though decreasing) to two years. Accordingly, the quality of life indicator can be used as an indicator of the effectiveness of PR and PT.

Evaluation of the results of PR and its effectiveness, according to the clinical setting [9], is based on an analysis of the perception of dyspnea, quality of life and physical performance. The prevalence of a particular research method of the presented indicators was not noted. To assess the level of dyspnea, the following research methods were proposed: a mMRC questionnaire, a baseline index of dyspnea (Baseline Dyspnea Index – BDI) and a transitional index of dyspnea (Transition Dyspnea Index – TDI), an oxygen cost chart, a CRQ questionnaire section on dyspnea. It is indicated that for assessing dyspnea on exertion, the Borg scale is most often used before and after the exercise test.

An assessment of the quality of life can be performed using CRQ, SGRQ, CAT, SF36 or its short version SF12. Changes in physical fitness are recommended to be evaluated using a 6-minute walk test. An alternative can be a shuttle walk test, but preference is given to bicycle ergometry with submaximal load [9].

In the clinical setting of Ian Yang (Ian Yang, 2016) [21], it is indicated that tests with a load on the cardiorespiratory system can be useful for differentiating the causes of shortness of breath (due to cardiac or respiratory illness), may help to identify other causes of constraints and to be useful for monitoring the results of medical or rehabilitation interventions. In particular, the 6MWD and shuttle tests allow you to evaluate blood oxygenation during exercise.

Summing up the analysis of selected clinical guidelines, it should be noted that only in GOLD-2017 [8] there is information on which tools can be used as diagnostic, prognostic criteria and criteria for selecting and monitoring the effectiveness of PR and PT. This does not apply separately to the PR process or the practice of PT, but to the healing and recovery process in COPD as a whole. In the remaining clinical guidelines there were recommendations on examination methods based on only one or two criteria. Yes, of course, mainly recommendations on the selection of examination tools relate to diagnosis, verification of the severity of the disease, and spirometry is the main method of research [3; 8; 14]. All recommendations on the use of diagnostic and therapeutic research methods are fairly general and do not define a specific list of indicators and research methods that should serve as tools for establishing a rehabilitation diagnosis, prognosis and monitoring the effectiveness of PT.

The research methods presented in clinical guidelines and individual indicators that are recommended to evaluate patients with COPD in the treatment and rehabilitation process can be grouped into the following groups (Figure 1):

1. Methods of investigation and indicators of the functional state of the respiratory and cardiovascular systems.
2. Assessment of the level of shortness of breath.
3. Assessment of quality of life and symptoms of COPD.
4. Assessment of the level of physical fitness.
5. Integral indicators.

To understand the complete picture of the physical, functional and psychoemotional state of a patient with COPD, it is advisable to use at least one of the research methods from each group.

As diagnostic criteria use methods for assessing the functional state of the respiratory and cardiovascular systems, indicators for assessing the level of dyspnea, quality of life and physical performance. The conclusion about participation in the PR program is mainly based on research methods and indicators of the functional state of the cardiorespiratory system and the assessment of the level of dyspnea. The prognostic criteria can be research methods and indicators from the group of the functional state of the cardiorespiratory system, assessment of the level of dyspnea and symptoms of COPD, and integral indicators. The research methods for all groups, except for integral indicators, are recommended to be used to select the PR/PT strategy and evaluate its effectiveness.

Conclusions / Discussion

Most of the recommendations for the use of research methods for patients with chronic obstructive pulmonary disease are reasonable for diagnosing, predicting and choosing a strategy for medical treatment and oxygen therapy. In the

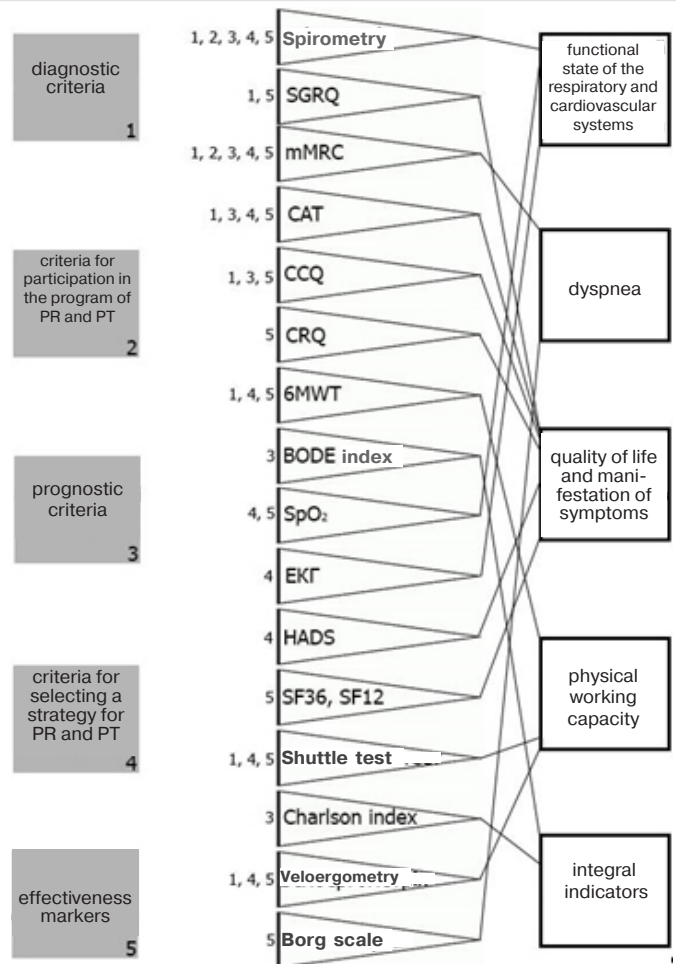


Figure 1. Categories and groups of indicators by which it is recommended to evaluate patients with COPD (analysis of clinical guidelines)

analyzed clinical recommendations, prognostic criteria are presented to predict the risk of exacerbations and mortality. Indicators on which to estimate (predict) the possible effect of intervention, in particular, physical therapy, not considered.

Most of the recommendations are not sufficiently focused on the application of research methods and indicators as prognostic criteria and markers of current and long-term effectiveness of physical therapy. All research methods described in the analyzed clinical guidelines, physical therapists can use in their practice. It is necessary to determine the value of each of the presented indicators in the process of PR and PT, to justify and methodically ensure the process of their use at all stages of pulmonary rehabilitation and physical therapy.

There are groups of research methods and indicators, with the help of which it is recommended to evaluate patients with COPD in the stages of diagnosis, selection of patients, prediction of the course of the disease, the choice of the strategy of the program of pulmonary rehabilitation and evaluation of its effectiveness.

Prospects for further research. Analyze the research methods and indicators that are most often used to evaluate patients with COPD in the process of pulmonary rehabilitation and physical therapy according to the proposed division into groups.

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