Abstract

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**CLINICAL AND FUNCTIONAL INDICATORS OVER TIME
IN OVERWEIGHT PATIENTS WITH BRONCHIAL ASTHMA
RECEIVING STANDARD THERAPY VS. STANDARD
THERAPY WITH A COMPLEX OF REHABILITATION
MEASURES**

The combination of bronchial asthma and obesity leads to increased severity of bronchial asthma course and poorer control level, the development of resistance to basic therapy, and increased frequency of hospitalizations. Modern approaches to the treatment of bronchial asthma and obesity suggest that more attention should be paid to comprehensive rehabilitation programs using methods aimed at all pathogenesis stages of this combination of diseases.

Objective: to analyze changes in clinical and functional indicators over time in overweight patients with bronchial asthma receiving standard therapy vs. standard therapy with a complex of rehabilitation measures

Materials and methods. The study involved 102 overweight patients (body mass index (BMI) ≤ 39.9 kg/height, m²) with persistent asthma of moderate severity aged 35–60 years. The patients were divided into 2 groups. Group I included 72 patients receiving standard pharmacologic therapy (budesonide 160 µg and formoterol 4.5 µg) along with a diet close to the Mediterranean diet, as well as a complex of rehabilitation measures, which included Buteyko breathing technique plus respiratory gymnastics and dosed walking. Group II (30 patients) received only standard pharmacologic therapy along with a diet close to the Mediterranean diet. The duration of the therapy was 6 months. All patients underwent general clinical studies, spirometry, the 6-minute walk test (6MWT) with dyspnea assessment according to the Borg Dyspnoea Scale, surveys using the Asthma Control Questionnaire-5, St George's Respiratory Questionnaire (SGRQ), Beck Depression Inventory, and Spielberger–Khanin Anxiety Inventory.

Results. It was found that the patients receiving treatment along with physical rehabilitation measures presented with more pronounced positive changes, so the indices of FVC and 6MWT medians in Group I were 6 times and 2.4 times higher, respectively. The changes in ACQ5, SGRQ, BDI, and SAI-t score medians in Group I were also more prominent and exceeded the values in Group II by 1.8 times, 4.4 times, 2.5 times, and 3.5 times, respectively.

Conclusions. Inclusion of physical rehabilitation measures, i.e. Buteyko breathing technique, respiratory gymnastics, and dosed

walking, contributes to a significant increase in FEV₁ and statistically significant improvement in quality of life and psychological status after 6 months of therapy.

Keywords: bronchial asthma, overweight, clinical and functional indicators, treatment efficacy.

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Резюме

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КЛІНІКО-ФУНКЦІОНАЛЬНІ ПОКАЗНИКИ ХВОРИХ НА БРОНХІАЛЬНУ АСТМУ З ПІДВИЩЕНОЮ МАСОЮ ТІЛА В ДИНАМІЦІ СТАНДАРТНОГО ЛІКУВАННЯ І СТАНДАРТНОЇ ТЕРАПІЇ, ДОПОВНЕНОЇ КОМПЛЕКСОМ ЗАХОДІВ ФІЗИЧНОЇ РЕАБІЛІТАЦІЇ

Вступ. Поєднання бронхіальної астми та ожиріння призводить до зростання тяжкості перебігу бронхіальної астми, зниження рівня її контролю, розвитку резистентності до базисної терапії, підвищення частоти госпіталізацій. У сучасних схемах лікування бронхіальної астми та ожиріння слід приділити більше уваги комплексним реабілітаційним програмам з використанням методів, спрямованих на всі ланки патогенезу даного поєднання захворювань.

Мета. Аналіз клініко-функціональних показників хворих на бронхіальну астму з підвищеною масою тіла в динаміці стандартного лікування і стандартної терапії, доповненої комплексом заходів фізичної реабілітації.

Матеріали і методи дослідження. У дослідженні взяли участь 102 хворих на персистентну БА середнього ступеня тяжкості з підвищеною масою тіла (індекс маси тіла (ІМТ) не більше 39,9 кг/ріст, м²) у віці 35–60 років. Хворих було поділено на дві групи. Перша група включала 72 пацієнта, які отримували стандартну медикаментозну терапію (160 мкг будесоніду і 4,5 мкг формотеролу) на тлі дієти, наближеною до середземноморської, а також комплекс реабілітаційних заходів, що включали дихання за методикою К. П. Бутейко, звукову гімнастику і дозовану ходьбу. Друга група, 30 пацієнтів, отримували тільки стандартну терапію на тлі дієти, наближеною до середземноморської. Тривалість лікування склала 6 місяців. Всім хворим було проведено загальноклінічні дослідження, спірографію, тест з 6-хвилинною ходьбою з оцінкою рівня задишки за шкалою Борга, анкетування за допомогою опитувальника Asthma Control Questionnaire-5, респіраторного опитувальника госпіталю SGRQ, опитувальників за шкалою депресії Бека і шкалою тривожності Спілбергера-Ханіна.

Результати дослідження. Встановлено, що в групі хворих, які отримували лікування з включенням заходів з фізичної реабілітації, відзначалася більш виражена позитивна динаміка. Так, показники медіан ФЖЕЛ і Т6Х в групі 1 були більше відповідно в 6 і в 2,4 раза. Динаміка змін за результатами тестів ACQ5, SGRQ, ШДБ, ШТС-р, ШТС-о у пацієнтів групи 1 також була більш виражена і перевищувала динаміку показників в групі 2 в 1,8 раза, 4,4 раза, 2,5 раза, 3,5 раза відповідно.

Висновки. Включення в комплекс лікування хворих на бронхіальну астму з підвищеною масою тіла засобів фізичної реабілітації, а саме: дихання за К. П. Бутейко, звукової гімнастики і дозованої ходьби, сприяє достовірному підвищенню ОФВ₁ і статистично достовірному покращенню показників якості життя і психологічного статусу через 6 місяців терапії.

Ключові слова: бронхіальна астма, підвищена маса тіла, клініко-функціональні показники, ефективність лікування.

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Introduction/Вступ

Bronchial asthma (BA) is a global unresolved medical and social problem. The disease is very common; it affects all age groups and can lead to worsening of quality of life and death (1, 2).

The World Health Organization estimates that about 358 million people suffer from BA, which is about 5% of the world's population (1, 3). The prevalence of asthma in different countries ranges from 7 to 25.5% and tends to increase progressively (4). Mortality due to BA also remains high and amounts to about 250 thousand cases per year (5).

To reduce the mortality rate, it is necessary to use all available resources in the management of BA patients with the obligatory inclusion of physical rehabilitation measures. However, this requires complex rehabilitation techniques and objective effectiveness criteria to be developed (6, 7). Today these issues are still far from being solved (8). Moreover, there are no standard programs for physical rehabilitation of patients with different BA phenotypes, for example, with a very common combination of BA and obesity (OB).

The combination of bronchial asthma and obesity leads to increased severity of bronchial asthma course and poorer control level, the development of resistance to basic therapy, and increased frequency of hospitalizations (9, 10). Scientific publications suggest numerous and complex pathogenetic relationships between BA and OB which explains the difficulties in achieving symptom control in this category of patients. This demonstrates the phenomenon of mutual aggravation of each disease comprising this

comorbidity (11). A large number of prospective epidemiological studies confirmed that obese patients not only have an increased risk of asthma, but also have more pronounced symptoms and require increased volume of therapy; they also seek emergency medical help more often than people with normal body weight (12, 13, 14). Abdominal obesity was found to contribute to the development of the respiratory system dysfunction, which involved an increased volume of soft tissues, increased blood volume in the lungs, and fatty infiltration in the chest (15). A number of authors point out that the risk factor for BA is represented not by the increased accumulation of fat itself, but rather by its location in the abdominal region (16). The BA-OB comorbidity has a clear negative effect on the BA symptoms control and the response to drug therapy in these patients is insufficient, while weight loss has a positive effect on achieving control over the disease (17).

There is no doubt that controlled physical activity need to be included into the treatment regimens for BA patients with OB. However, today the means of physical rehabilitation are used insufficiently in the management of BA patients with OB, and the criteria for their effectiveness require research (11), which makes this study relevant.

Objective: to analyze changes in clinical and functional indicators over time in overweight patients with bronchial asthma receiving standard therapy vs. standard therapy with a complex of rehabilitation measures.

Materials and methods. The study was conducted in 2018–2020 at the Pulmonology Department of the Municipal Non-Profit Enterprise "City Clinical Hospital No. 13" of the Kharkiv City Council (Kharkiv, Ukraine). The study involved 102 overweight patients (body mass index (BMI) ≤ 39.9 kg/height, m^2) with persistent asthma of moderate severity aged 35–60 years (mean age 52.64 ± 8.24). BA was diagnosed in accordance with the GINA guidelines (1). According to the type of therapy, the patients were divided into two groups comparable in age, body mass index (BMI = body weight, kg/height, m^2) and gender composition ($p > 0.05$). Group I included 72 patients receiving standard pharmacologic therapy (a fixed dose combination of budesonide 160 μg and formoterol 4.5 μg twice a day plus the same combination as a single inhaler dose additionally on request) along with a diet close to the Mediterranean diet, as well as a complex of rehabilitation measures. The complex of rehabilitation measures was represented by Buteyko breathing technique in the morning, respiratory gymnastics (2 times a day) and dosed walking once a day whenever convenient for the patient (18). Group II (30 patients) received only standard pharmacologic therapy along with a diet close to the Mediterranean diet. The duration of the therapy was 6 months. The exclusion criteria were: diabetes mellitus; acute and chronic infectious diseases; systemic, oncological, or mental diseases; chronic heart failure with a left ventricular ejection fraction of less than 45%; a history of myocardial infarction, stroke, or signs of coronary heart disease. The study was carried out in accordance with the Declaration of Helsinki of the General Assembly of the World Medical Association, EU Convention on Human Rights and Biomedicine, Good Clinical Practice (GCP), and relevant WHO guidelines and laws of Ukraine. All patients signed an informed consent form to participate in the clinical study.

All included patients were examined according to the program that included general clinical studies, spirometry (pulmonary function test) using SPIROCOM computer system (KHAI-Medica Research Institute, Kharkiv) (19) (only the most important parameters are discussed here: forced vital capacity measured at maximum forced expiration (FVC) and forced expiratory volume in the first second (FEV_1)), the 6-minute walk test (6MWT) (20) with dyspnea assessment according to the Borg Dyspnoea Scale (21) before and after 6MWT, the Asthma Control Questionnaire-5

(ACQ-5) (22) survey to determine the level of asthma symptoms control, St George's Respiratory Questionnaire (SGRQ) survey to assess asthma effect on general health, daily life, and well-being in patients with obstructive airway diseases (the questionnaire suggests an overall score from 0 to 100, where higher score indicates a higher level of negative effect; the SGRQ questionnaire includes three components: assessment of symptoms severity, limitation of physical activity, impact on social activity and psychological state. There is also a total indicator of the overall quality of life according to the SGRQ questionnaire (SGRQ QOL) (23). The psychological state of the patients was additionally evaluated using Beck Depression Inventory (BDI), and Spielberger–Khanin Anxiety Inventory (SAI) with state anxiety (SAI-s) and trait anxiety (SAI-t) assessment.

The obtained results were processed using Statistica program. The quantitative data were presented as a median (M) and interquartile range (IQR). The critical value of statistical significance level when testing null hypotheses equaled 0.05. To compare the central parameters of the groups, parametric and nonparametric methods were used: Student's t-test, Wilcoxon test and Mann–Whitney test. For pairwise comparison of groups, the Mann–Whitney U-test was used; the Spearman correlation coefficient was used to determine the relationship between paired data.

Results and discussion. To achieve the goal of the study, a comparative analysis was carried out for the effectiveness of treatment of BA patients with overweight depending on the treatment regimen. Evaluation of changes in the studied clinical and functional indicators over time performed in the group receiving treatment plus physical rehabilitation measures showed clear positive results. All the studied parameters demonstrated positive changes, though not always of statistical significance. The median FEV_1 and FVC increased significantly by 13.43% and 17.91%, respectively ($p < 0.05$). Significant positive changes were registered according to the results of SGRQ, BDI, SAI-s, SAI-t hospital questionnaires ($p < 0.05$). The decrease in median SGRQ, BDI, SAI-s, SAI-t scores was 20.2%, 39.13%, 4.99%, and 14.29%, respectively ($p < 0.05$). There was a significant decrease in ACQ5 median and increase in the 6MWT median which amounted 32.14% and 10.55%, respectively ($p < 0.05$). The data obtained indicated that after 6 months of complex treatment including physical

rehabilitation measures in patients with moderate asthma with overweight, the airflow in the respiratory system increased and the quality of life significantly improved. At the same time, a pronounced psychological stabilization was observed in patients due to the improved symptom control and increased exercise tolerance.

In the group of patients who received standard BA therapy along with a diet close to the Mediterranean diet, positive changes were also observed in the studied clinical and functional parameters; however, they were less pronounced and were not statistically significant ($p > 0.05$). This can be explained, on the one hand, by the lack of changes in therapy nature after inclusion into the study, and on the other hand, by the absence of rehabilitation measures in the treatment regimen. In group 2, the decrease in ACQ5, BDI, SAI-s, SAI-t, and SGRQ score medians equaled 17.86%, 15.79%,

0%, 4.04%, ($p > 0.05$) and 4.63%, respectively ($p < 0.05$). At the same time, there was a slight increase in FVL and 6MWT medians, which amounted 2.99% and 4.34%, respectively ($p > 0.05$).

The advantages of using physical rehabilitation measures in the treatment of moderate BA patients with overweight were even more clearly demonstrated by the difference in the degree of median changes observed for the studied clinical and functional parameters. The values of positive over-time changes in FVC and 6MWT medians in Group I were 6 times and 2.4 times higher, respectively. The changes in ACQ5, SGRQ, BDI, and SAI-t score medians in Group I were also more prominent and exceeded the values in Group II by 1.8 times, 4.4 times, 2.5 times, and 3.5 times, respectively. The study results are presented in Table 1.

Table 1 – Changes in clinical and functional indicators over time in overweight patients with bronchial asthma receiving different treatment regimens (median, interquartile range)

Parameter	Group I (n = 72) Before treatment	Group I (n = 72) After treatment	Group II (n = 30) Before treatment	Group II (n = 30) After treatment
ACQ5, points	1.40 [1.1–1.6]	0.95 [0.78–1.3]*	1.40 [1.1–1.6]	1.15 [0.80–1.95]
FEV ₁ , %	67.0 [62.0–71.5]	76.0 [69.0–80.0]*	67.0 [61.0–70.0]	67.0 [63.0–74.0]
FVC, %	67.0 [58.0–79.5]	79.0 [67.5–88.5]*	67.0 [63.0–74.0]	69.0 [61.0–78.0]
6MWT, m	422.0 [400.0–498.0]	466.5 [425.0–510.0]*	426.5 [400.0–510.0]	445.0 [400.0–506.0]
SGRQ QOL	54 [41–59]	43.09 [29.4–55.53]*	54 [41–59]	51.5 [39–56]*
BDI, points	11.5 [6–16]	7 [5–12]*	9.5 [6–15]	8 [6–11]
SAI-t, points	45.5 [28–62.5]	39 [27–57.5]*	49.5 [27–64]	47.5 [34–55]
SAI-s, points	44.9 [26.3–58.2]	42.66 [23.75–56.46]*	47.5 [35–58]	47.5 [32–56]

Note: * – a statistically significant difference when comparing before and after treatment ($p < 0.05$)

The complex of rehabilitation measures was represented by Buteyko breathing technique, respiratory gymnastics, and dosed walking. In addition to general strengthening properties, these measures were aimed at restoring the functions of the respiratory system, whereas dosed walking in combination with a diet can both initiate and maintain body weight loss (26, 27).

Conclusions/Висновки

1. Inclusion of physical rehabilitation measures, i.e. Buteyko breathing technique, respiratory gymnastics, and dosed walking, contributes to a significant increase in FEV₁ and statistically significant improvement in quality of

Since positive changes in the clinical and functional state of BA patients with overweight dominated in the therapy group using physical rehabilitation measures, we suggest the need to develop and introduce complex individual approaches with the obligatory inclusion of rehabilitation programs into the treatment regimens for this group of patients.

life and psychological status after 6 months of therapy.

2. In overweight patients with moderate asthma utilizing a complex of rehabilitation measures, the degree of positive changes in the ACQ5 symptom control was 27 times higher, which indicated a high sensitivity of the parameter to physical

rehabilitation measures and a close relationship between the latter and BA symptom control.

3. Inclusion of physical rehabilitation measures, i.e. Buteyko breathing technique, respiratory gymnastics, and dosed walking, in the complex therapy of overweight patients with

moderate asthma leads to an increased functional capabilities of the respiratory system with better control of asthma symptoms, increased exercise tolerance, an improvement in the psychological status of patients with a pronounced improvement in their quality of life after 6 months of treatment.

Prospects for future research/Перспективи подальших досліджень

It is advisable to study further the criteria for the effectiveness of physical rehabilitation measures and their inclusion in the complex therapy of overweight patients with bronchial asthma, which

contributes to an increase in the functional capabilities of the respiratory system with better control of asthma symptoms.

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Conflict of interest/Конфлікт інтересів

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