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The Application of High-Intensity and Low-Intensity Magnetotherapy in the Rehabilitation of Patients with COVID-19: A Randomized Controlled Pilot Study

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Background. The rehabilitation of patients after severe pneumonia associated with the new coronavirus infection requires searching for effective tools to restore impaired functions, including physiotherapy methods. **Aims:** To assess the effectiveness of the usage of a high-intensity electromagnetic field (HIEF) in the aftercare of patients recovering from COVID-19-associated pneumonia. **Methods.** There were 40 patients examined and treated at the outpatient stage of rehabilitation after severe pneumonia associated with COVID-19. All patients received a set of rehabilitation measures, including daily sessions of therapeutic exercises (No. 15) and magnetotherapy procedures (No. 15). Patients were randomly separated into 2 groups: 20 patients in the treatment group (TG) who received HIEF therapy (BTL-6000 Super Inductive System) and 20 patients in the control group (CG) who received low-intensity magnetotherapy (BTL-4000 Premium device). **Results.** During the course of therapy, there were no patients who dropped out of the study, and no undesirable side effects or complications were identified. Our set of combined aftercare measures has been proven to be highly clinically effective. The overall effect was more pronounced in the HIEF-treated group. The results were confirmed by the reliable dynamics of clinical indicators according to the valid questionnaire and positive changes in spirometry data. **Conclusions.** The application of a high-intensity electromagnetic field is advisable in the complex outpatient rehabilitation of patients after severe pneumonia associated with COVID-19.

Keywords: COVID-19, pneumonia, magnetotherapy, high-intensity electromagnetic field, physical and rehabilitation medicine.

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Abbreviations

electromagnetic field

HIEMF: high-intensity electromagnetic field CT 1-4: a unified standard for viral pneumonia classification according to severity CAPSQ: Community-Acquired Pneumonia Symptom Questionnaire FVC: forced vital capacity

FEV1: forced expiratory volume in 1 second MGT (magnetic therapy): low intensity magnetic therapy SIS (super inductive system): high-intensity

Justification

The emergence and spread of the new coronavirus infection necessitate the need to improve medical measures, including rehabilitation stages following severe forms of the disease [1]. It has been established that SARS-CoV-2 associated pneumonia assumes a severe course in a significant number of patients, often with other vital organs and systems dysfunctional, persistent disorders of the respiratory function and the oxygen transport function of blood and blood vessels. The convalescents make up a clinical picture associated with a number of residual conditions, one of which is a respiration pattern abnormality [2]. Particularly significant disorders of respiratory movement mechanics develop following artificial ventilation. Diaphragm dysfunction, a weakening of intercostal and other muscles involved in breathing, under conditions of general muscle weakness,

Применение магнитотерапии высокой и низкой интенсивности в реабилитации пациентов с COVID-19: рандомизированное контролируемое пилотное исследование

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Обоснование. Реабилитация пациентов после тяжелых пневмоний, ассоциированных с новой коронавирусной инфекцией, требует поиска эффективных инструментов восстановления нарушенных функций, в том числе методов аппаратной физиотерапии. Цель исследования — оценить эффективность применения высокоинтенсивного электромагнитного поля (ВИМП) в реабилитации пациентов после перенесенной пневмонии, ассоциированной с COVID-19. Методы. На амбулаторном этапе реабилитации после тяжелых пневмоний, ассоциированных с COVID-19, проведено обследование и лечение 40 пациентов. Все пациенты получили комплекс реабилитационных мероприятий, включая ежедневные сеансы лечебной гимнастики (№ 15) и процедуры магнитотерапии (№ 15). Пациенты были случайным образом рандомизированы на 2 группы: 20 пациентов в группе лечения, которые получали терапию ВИМП (аппарат BTL-6000 Super Inductive System), и 20 пациентов в группе контроля, получавшие низкоинтенсивную магнитотерапию (аппарат BTL-4000 Premium). Результаты. В ходе проводимой терапии ни один пациент не выбыл из исследования, не было выявлено нежелательных побочных эффектов и осложнений. Доказана высокая клиническая эффективность комплекса реабилитационных мероприятий, более выраженная в группе пациентов, получавших терапию ВИМП. Результаты подтверждены достоверной динамикой клинических показателей по данным валидного опросника и положительными изменениями данных спирометрии. Заключение. В комплексной реабилитации на амбулаторном этапе у пациентов после тяжелой пневмонии, ассоциированной с COVID-19, целесообразно использование ВИМП.

Ключевые слова: COVID-19, пневмония, магнитотерапия, высокоинтенсивное электромагнитное поле, физическая и реабилитационная медицина.

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lead to a decrease in ventilation parameters, aggravating disorders caused by specific changes in the lung tissue.

Special breathing exercises play the most important role during each stage of the rehabilitation measures [3-5]. In addition, the use of physical treatment methods, including various types of electromagnetic stimulation or magnetotherapy, is of great importance [6]. The therapeutic use of low-intensity magnetotherapy stimulates the vasodilatory and bronchodilatory effects, and it reduces the inflammatory response [7-9]. When stimulated by a high-intensity (1-2 T) electromagnetic field (HIEMF), the action potential of motoneurons is additionally activated, which leads to muscle contraction [10-12]. The possibility of HIEMF to noninvasively improve respiratory muscle function [13-15] and the pulmonary ventilation parameters has been described [16-18].

The purpose of the study is to evaluate the effectiveness of a high-intensity electromagnetic field in the rehabilitation of patients following COVID-19 associated pneumonia.

Methods Study design

This was a randomized controlled pilot study. The study involved 40 patients undergoing a rehabilitation program following COVID-19 associated pneumonia (3rd outpatient stage). Patients were randomly assigned to 2 groups: 20 patients in the treatment group and 20 patients in the control group.

Eligibility criteria

Entry criteria: The patient's adult age (\geq 18 years); SARS-CoV-2 confirmed by laboratory assessment; computed tomography confirmed bilateral polysegmental pneumonia of at least moderate severity (at least CT-2); a decrease in external respiration parameters as confirmed by spirometry.

Exclusion criteria: Increased body temperature > 37.5° C; negative dynamics of computed tomography data and/or inflammation markers; negative dynamics of electrocardiograms during the previous 2 weeks; high cardiac risks; thrombosis or blood coagulation disorders requiring

additional therapy; PO_2 saturation (oxygen partial pressure) < 95%; decrease in PO_2 by more than 4 points during exercise stress; metal implants, pacemaker or other internal electronic devices, as well as general contraindications to physiotherapy.

Study setting

The study was based at the Rehabilitation Department in the Clinical Hospital "Lapino" of the "Mother and Child" Group of Companies (Moscow, Russia).

Study duration

The study was conducted within the period from April to June 2020. COVID-19 pneumonia associated patients, who underwent inpatient treatment at the Clinical Hospital "Lapino" during the 1st wave of the pandemic, after completing a 2-week period of self-isolation for 15 days (15 daily visits) received a comprehensive outpatient rehabilitation in the relevant hospital department.

Description of the medical intervention

Before starting treatment, in order to exclude contraindications, all patients underwent an examination: a SARS-COV-2 test using a polymerase chain reaction; multispiral computed tomography of the chest cavity organs; clinical, general and biochemical blood tests (including highly sensitive C-reactive protein and interleukin 6), coagulogram and D-dimer; electrocardiography; consultation with a pulmonologist.

The comprehensive rehabilitation included 15 daily visits. At the same time, patients from both groups received individual breathing exercises with a physiotherapy instructor for 30 minutes. The course of therapeutic exercises included 15 procedures. Immediately after the exercises, the patients received magnetotherapy procedures.

Patients in the treatment group underwent HIEMF therapy (BTL-6000 Super Inductive System, Great Britain), the purpose of which was to stimulate the diaphragm and intercostal muscles with a subsequent increase in blood circulation. Patient position was lateral. Localization of exposure: The inductor was placed on the dorsal side of the body (in the area between the 1st-6th ribs) sequentially on the right and on the left. A breathing improvement program was used. The intensity of the therapy was set above the level of the motor threshold, but within a range comfortable for the patient, until there was a motor reaction that intensified inhalation (every other day, No. 8) and exhalation (every other day, No. 7), sequentially on the right and on the left. The course included 15 daily procedures.

Patients in the control group received low-intensity magnetotherapy (BTL-4000 Premium, Great Britain) in order to improve blood circulation. The patients' position was the ventricumbent position. Localization of exposure: There were 2 independent inductors placed on the projection area of the lower 2/3 of the lung on both sides. The duration was 30 minutes. The course included 15 daily procedures.

Study outcomes

All patients in both groups completed the prescribed course of treatment. No side effects or pain were reported.

Outcome registration methods

The examination of patients started with a survey, including a clarification of complaints presented by patients; a study of their medical history; a general clinical examination. The examination included a set of modern clinical-functional and instrumental methods approved for use in medical practice, including before and immediately after the completion of the rehabilitation program, all patients underwent an assessment of the respiratory function (spirometry) (BTL Cardiopoint-Spiro, BTL Industries Ltd.) and completed the CAPSQ (Community-Acquired Pneumonia Symptom Questionnaire) questionnaire on the symptoms of community-acquired pneumonia [19]. The data obtained were subjected to statistical analysis.

Ethical review

The study was conducted in accordance with the principles of Good Clinical Practice (GCP) and applicable national regulations, respecting the rights, safety and well-being of study subjects, who were protected by the ethical principles set forth in the Helsinki Declaration. A voluntary written informed consent was obtained from each subject prior to the study. Each study subject was informed in writing of the nature and duration of the treatment and rehabilitation measures, as well as the expected results of the treatment.

Statistical analysis

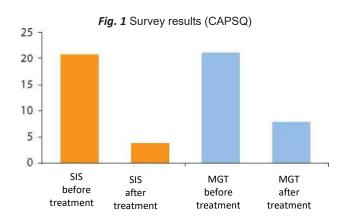
All the results obtained were processed using the Microsoft Office Excel (2010) program and a package of applied statistical programs for biomedical research STATISTICA 10,0/W RUS. The one-way ANOVA test and the Mann-Whitney test were used to analyse quantitative variables; analysis of categorical variables was performed using Pearson's χ^2 test. The results of the statistical analysis are presented as M±SD, where M is a mean, SD is a standard deviation. The significance of differences (*p*) within the group obtained during the observation period was assessed using the Wilcoxon rank sum test. The differences were considered significant at <0.05.

Results Study subjects

A total of 40 patients were examined. The main group (treatment group; n=20) consisted of 16 male subjects, 4 female subjects, average age of 56.6 ± 11.9 years. The control group (n=20) consisted of 14 male subjects, 6 female subjects, average age of 57.9 ± 11.8 years. As part of the comprehensive rehabilitation, patients in the treatment group received HIEMF therapy (BTL-6000 Super Inductive System device), while patients in the control group received low-intensity magnetotherapy (BTL-4000 Premium device). In terms of age, concomitant diseases, the severity of pneumonia, and the results of the examination preceding rehabilitation measures, the patients in the groups being studied were statistically homogeneous.

Key study findings

The rehabilitation program led to an improvement in the well-being of patients in both groups, which was confirmed by the significant reliable dynamics of parameters in a specialized questionnaire on the symptoms of community-acquired pneumonia (p<0.001).



Note. CAPSQ: Community-Acquired Pneumonia Symptom Questionnaire; SIS (super inductive system): treatment group using a high-intensity (1-2 T) electromagnetic field; MGT (magnetic therapy): low-intensity magnetotherapy in the control group.

Positive clinical dynamics were accompanied by positive changes in spirometric parameters in both groups (p<0.05). A comparison of the treatment results between groups showed significant reliable differences (in points) in the symptoms of community-acquired pneumonia (Fig. 1) and according to spirometry data (p<0.05). Thus, in the treatment group, an improvement was achieved in FVC by 12.4%, FEV1 — by 16.3% (Fig. 2) and FEV1/FVC — by 4%, respectively (Fig. 3),

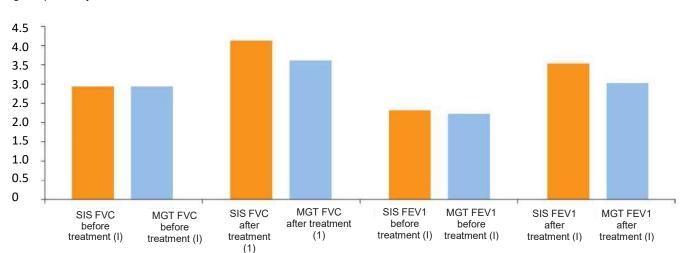
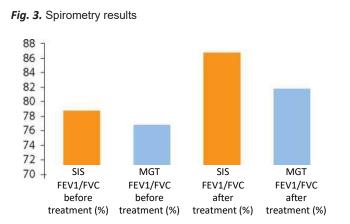


Fig. 2 Spirometry results

Note. SIS FVC/SIS FEV1: forced vital capacity/forced expiratory volume in one second parameters during treatment with a highintensity (1-2 T) electromagnetic field; MGT FVC/MGT FEV1: forced vital capacity/forced expiratory volume in one second parameters against the background of low-intensity magnetotherapy in the control group.



Note. SIS (super inductive system): treatment group using a highintensity (1-2 T) electromagnetic field; MGT (magnetic therapy): low-intensity magnetic therapy in the control group; FVC/FEV1: forced vital capacity/forced expiratory volume in one second.

exceeding similar parameters of spirometry in the control group, where FVC is forced vital capacity; FEV1 is forced expiratory volume in 1 sec.

Treatment group results. A comparison of the CAPSQ questionnaire score before and immediately after treatment showed significant reliable changes (p<0.001): 20.8±7.0 and 3.7±3.9 points, respectively.

An analysis of spirometry data in the dynamics of treatment showed significant (p<0.001) changes in FVC, FEV1 and their ratio (FEV1/FVC). The FVC values before therapy were 2.9±0.8 L, or 73.5±10.3%, after treatment 4.1±1.1 L, or 102.8±11.8%. The overall improvement was 29.3%. The FEV1 values before treatment were 2.3±0.6 L, or 69.4±8.7%, after treatment 3.5±0.9 L, or 107.1±14.4%. The overall improvement was 37.7%. A comparison of the FEV1/FVC ratio (%) before and after treatment was also significant (p<0.001): 78.6±6.9 L, or 98.9±9.0%, and 86.6±5.8 L, or 109.3±9.1%, respectively. The improvement was 10.4%.

Control group results. In the control group, changes in the parameters of questionnaires and spirometry that occurred in the dynamics of treatment were unidirectional compared with the treatment group, but less significant. However, significant differences were shown by a comparison of CAPSQ scores (21.2±6.9 and 7.8±3.7 points before and after treatment, respectively) and a comparison of assessment data for the respiratory function (p<0.001). Thus, when comparing FVC, FEV1 and their ratio before and after the intervention, the following results were obtained: FVC before treatment was 2.9±0.8 L, 67.6±10.2%, after treatment 3.6±0.7 L, 84.5±6.8%, overall improvement was 16.9%; FEV1 before treatment was 2.2±0.6 L, 66.0±11.4%, after treatment 3.0±0.6 L, 87.4±7.9%, overall improvement was 21.4%; FEV1/FVC (%) before treatment 76.6±5.4%, 96.2±6.0%, after treatment 81.7±3.7%, 102.6±3.9%, overall improvement was 6.4%.

Discussion

Summary of the main study's findings

According to the data obtained, the use of comprehensive rehabilitation at the outpatient stage in patients after severe (at least CT-2) polysegmental COVID-19 associated pneumonia leads to a significant clinical improvement and parameter recovery of the respiratory function. Inclusion into the rehabilitation program of an innovative therapy method of a high-intensity electromagnetic field increases the effectiveness of rehabilitation measures.

Discussion of the main study's findings

Dynamic observation of patients in the study groups showed significant, positively directed differences in clinical parameters confirmed by questionnaire data and spirometry parameters studied before and after treatment. It is important to emphasize that the comparison between the groups showed significant differences in the degree of the effect achieved. Thus, the clinical dynamics and the dynamics of the external respiration function parameters were significantly more pronounced in the treatment group.

Today, there is no doubt about the effectiveness of physical exercise during the rehabilitation stage in patients after severe COVID-19 associated pneumonia. However, the respiratory muscle dysfunction, including acquired diaphragm weakness, requires painstaking individual work by qualified personnel in neuromuscular retraining, and recovery of the optimal respiratory movements pattern. The emergence of a noninvasive technology that purposefully induces contraction of the diaphragm itself and other muscle groups involved in the respiratory movements provides conditions for the rapid rehabilitation of these difficult-to-control parts of the skeletal muscles. The possibility of improving external respiration function by stimulating the respiratory muscles has been shown using HIEMF in patients with neurological diseases. Our study's findings showed the exceptional HIEMF efficacy in the respiratory rehabilitation of patients after severe COVID-19 associated pneumonia.

Study restrictions

To the best of the author's knowledge, this is the first study suggesting that HIEMF can be used to improve ventilation parameters in patients after severe COVID-19 associated pneumonia. Based on the findings of this pilot study, we suggest that HIEMF can and should be integrated into the rehabilitation of these patients. At the same time, this technology will be in highest demand in the severe category of patients with the most pronounced respiratory muscle dysfunction. This pilot study provides a framework to develop long-term HIEMF studies with the examples of other patient populations to further determine its clinical efficacy.

Conclusion

HIEMF is a non-invasive, highly effective treatment method that is well tolerated by patients after severe COVID-19 associated pneumonia, and it does not require high labour costs or consumables. In the comprehensive rehabilitation during the outpatient stage, not a single patient after severe COVID-19 associated pneumonia withdrew from the study, and no side effects or complications were identified. The high clinical effectiveness of this method has been proven.

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The authors of this article have declared no conflicts of interest.

Contribution of authors

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