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The new therapeutic complex for the treatment of unstable stenocardia at the presence of type 2 diabetes mellitus and hyperventilation syndrome: elaboration and analysis of efficiency based on the assessment of outcomes

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Abstract

The article presents data from an original study on the implementation and empirical verification of the effectiveness of the developed therapeutic complex aimed at improving the intensive treatment of the nosological association «unstable angina pectoris (as the underlying disease) + type 2 diabetes mellitus (as a background pathology) + hyperventilation syndrome (as a concomitant state)». The author's therapeutic complex is based on a controlled change in auxiliary respiratory oxygenation «downward», provided that basic pharmacotherapy must be supplemented with a balanced combination of antihypoxic drugs and antiaggregant of new generation. A comparative study of two groups of thematic patients was carried out - using the developed complex and using the «traditional approach». The complex key parameters of the outcomes of the underlying disease in patients were studied using clinical assessment of functional classes of angina pectoris and veloergometric assessment of exercise tolerance. When using the developed therapeutic complex in comparison with the «traditional approach», a fundamental improvement in the outcomes of angina pectoris was established, which was confirmed by both the ratio of functional classes and the results of bicycle ergometry. The obtained data of intergroup differences have a high level of statistical significance. This proved the significant actual effectiveness of the developed therapeutic complex. The data presented in the article are distinguished by novelty and practical applicability, which makes it possible to recommend them for further implementation in the practice of the clinic of internal diseases.

Keywords: hyperventilation syndrome (HVS), unstable stenocardia, diabetes mellitus, therapeutic complex, elaboration, outcomes.

Аннотация

В статье представлены данные оригинального исследования по реализации и эмпирической проверке эффективности разработанного терапевтического комплекса, направленного на улучшение интенсивного лечения нозологической ассоциации «нестабильная стенокардия (в качестве основного заболевания) + сахарный диабет второго типа (в качестве фоновой патологии) + гипервентиляционный синдром (в качестве сопутствующего состояния)». Авторский терапевтический комплекс основан на контролируемом изменении вспомогательной респираторной оксигенации «в сторону уменьшения» при условии обязательного дополнения базисной фармакотерапии сбалансированной комбинацией препаратов антигипоксического действия и дезагрегантом нового поколения. Проведено сравнительное исследование двух групп тематических пациентов – с применением разработанного комплекса и с использованием «традиционного подхода». Изучены комплексные ключевые параметры исходов основного заболевания у пациентов – с помощью клинической оценки функциональных классов стенокардии и велоэргометрической оценки толерантности к физической нагрузке. При использовании разработанного терапевтического комплекса по сравнению с «традиционным подходом» установлено принципиальное улучшение исходов стенокардии, что подтверждено как соотношением функциональных классов, так и результатами велоэргометрии. Полученные данные межгрупповых различий имеют высокий уровень статистической значимости. Это доказало значительную фактическую эффективность разработанного терапевтического

комплекса. Представленные в статье данные отличает новизна и практическая применимость, что позволяет рекомендовать их к дальнейшему внедрению в практику клиники внутренних болезней.

Ключевые слова: нестабильная стенокардия, сахарный диабет, гипervентиляционный синдром, терапевтический комплекс, исходы.

Actuality. Unstable angina pectoris, being a typical variant of ischemic heart disease with acute coronary syndrome (ACS), from the point of view of medical and social significance, continues to occupy an exceptional position in the structure of modern somatic pathology [1, 2, 3]. One of the main unresolved aspects of this problem is the presence of the so-called conditions «comorbid» in relation to ischemic heart disease [4, 5], among which diabetes mellitus of the second type has one of the highest values in the population [6]. However, despite some known data that angina pectoris against its background takes on a more severe course and prognosis [7], no clarifying statistical studies regarding this situation in ACS have been performed to date. The so-called hyperventilation syndrome, which plays the role of a pathogenetic factor that has not been studied so far, which, nevertheless, complicates the course of various forms of pathology [8, 9, 10, 11, 12, 13]. Its real value has been underestimated for a long time, but at the present stage, the attention of clinicians to it is steadily increasing [14, 15]. It should be noted that, despite the obvious perceived prerequisites for its special clinical and pathogenetic significance in acute coronary syndrome (including unstable angina pectoris), it is in this respect that it has been extremely insufficiently studied. As a result of the theoretical analysis of the range of designated IHD-oriented problems, it should be noted that studies devoted to the combination of all three of the above pathological conditions have practically not been carried out to date. Thus, the clinical situation of unstable angina pectoris against the background of type 2 diabetes mellitus and with concomitant hyperventilation syndrome is a complex and, at the same time, practically unresolved problem. In its aspect, the most interesting is the optimization of treatment and the study of the outcome of pathology [16], however, the results of such studies in the available information sources have not been found either. In connection with the above circumstances, the topic of this study is quite relevant.

Purpose. To develop a therapeutic complex adapted for the treatment of the nosological association «unstable angina pectoris + type 2 diabetes mellitus + hyperventilation syndrome», followed by an integral assessment of its effectiveness based on the analysis of outcomes.

Materials and methods. The study involved 200 people who corresponded to the patient's model: «IHD, unstable angina pectoris, type 2 diabetes mellitus (stage of compensation), hyperventilation syndrome, in the age 50-80 years». The initial sample was divided into 2 contrast groups of 100 people, differing in the type of treatment program used:

- group 1 («control», $n_1 = 100$ people) – using only basic treatment in the so-called «traditional approach» format;
- group 2 («main», $n_2 = 100$ people) – with the use of the developed therapeutic complex in addition to the basic treatment.

The basic treatment included auxiliary oxygenation, infusion therapy, the use of nitroglycerin preparations, β_1 -blockers, multimodal analgesia (partial opioid receptor agonists + nonsteroidal anti-inflammatory compounds), heparin therapy, glucose-potassium-magnesium-insulin mixture, and was carried out in accordance with the recommendations of the Russian Federation Ministry of Health and the Russian Society of Cardiology.

The predominant route of administration of pharmacological drugs in both groups is intravenous. The elaborated therapeutic complex is a practical implementation of the author's concept of targeted correction of hyperventilation syndrome in the form of a controlled change in auxiliary respiratory oxygenation «downward» (with «target» parameters: $pO_2 = 44-46$ mm Hg, $pCO_2 = 38-40$ mm Hg, $St_aO_2 = 94-95\%$) subject to the obligatory addition of basic pharmacotherapy with a balanced combination of antihypoxic drugs (it included mildronate,

riboxin, nicotinamide, riboflavin, succinic acid and α -lipoic acid) and a new generation antiaggregant – clopidogrel.

The investigated integral indicators of disease outcomes: 1) functional class of angina pectoris, 2) level of exercise tolerance. Both indicators are determined at the end of the period of inpatient treatment (immediately before discharge).

Methods for obtaining primary data: 1) determination of functional classes of angina pectoris (FC), 2) veloergometry (VEM).

Technical equipment for obtaining primary data: 1) Classification of functional classes of angina pectoris of the Canadian Cardiological Society (1976), 2) exercise vloergometric complex «Valenta» («NevaTrade», Russia, St. Petersburg), veloergometric complex – stress-system «KARDIOTECHNIKA» («Inkart», Russia).

Methods of statistical analysis of primary data: Shapiro-Wilk W -test, method of comparing observed and expected frequencies using Pearson's χ^2 -test. The minimum accepted level of statistical significance of intergroup differences in complication rates is $p < 0,05$ [17, 18]. The calculation and documentation of the results obtained were carried out using a personal computer with StatSoft Statistica 6.0 software.

Results. *Investigation of the formation of a functional class of angina pectoris.* At the stage of discharge from the hospital, the distribution of outcomes by gradation in the groups had statistically significant differences: in the control group: FC I – 7%, FC II – 37%, FC III – 56%, in the main group: FC I – 34%, FC II – 35%, FC III – 31%.

When comparing the quantitative distributions of the outcomes of unstable angina pectoris hyperventilation syndrome in groups using the «traditional approach» and the developed therapeutic complex in the latter case, the results appeared to be much better.

A high level of statistical significance of differences between the observed («traditional approach») and expected («elaborated therapeutic complex») frequencies of outcomes of unstable angina pectoris was revealed: $\chi^2 = 41,71675$, $df = 2$, $p < 0,000000$.

The group of patients using the «traditional approach» is most characterized by the third functional class, the second and the first functional classes occupy the 2nd and 3rd places, respectively.

The group of patients with the developed therapeutic complex is most characterized by the second functional class, while the first and third functional classes occupy the 2nd and 3rd places, respectively.

The number of patients with FC I increased compared with that in the control group – 4,86 times, the number of patients with FC II, on the contrary, decreased 1,06 times, with FC III – 1,81 times.

Investigation of the formation of "final" VEM-tolerance to physical loading. At the stage of discharge from the hospital (10th day of observation), the distributions of outcomes by gradation in the groups had statistically significant differences: in the control group: high (> 100 W) – 9%, medium (26-100 W) – 36%, low (< 25 W) – 55%, in the main group: high (< 25 W) – 32%, medium (26-100 W) – 36%, low (> 100 W) – 32%.

A high level of statistical significance of differences between the observed («traditional approach») and expected («developed therapeutic complex») frequencies of gradation of exercise tolerance was revealed: $\chi^2 = 33,06250$, $df = 2$, $p = 0,000000$.

The group of patients using the «traditional approach» is most characterized by low tolerance (55%), medium and high are ranked the 2nd (36%) and 3rd (9%), respectively. The group of patients with the developed therapeutic complex is most characterized by the average degree of tolerance (36%), while low and high «share» the 2nd place (by 32%, respectively). As a result, the number of patients with high tolerance is increased by 3,56 times compared to that in the control group, the number of patients with low tolerance, on the contrary, is reduced by 1.72 times, the number of patients with medium tolerance remains unchanged.

Conclusion. The data obtained indicate a statistically confirmed positive effect of the developed therapeutic complex on the outcomes of unstable angina pectoris against the background of type II diabetes mellitus and with concomitant hyperventilation syndrome. This is confirmed by the duplicating criteria for the integral assessment of the outcome – the formation of the functional class of angina pectoris and the level of tolerance in physical activity – at the end of the period of inpatient treatment (while the results of assessing the outcome using the two alternative methods coincide). The results achieved in this study make it possible to recommend the developed therapeutic complex for implementation in healthcare practice.

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Electronic microscopic research of the surface of the teeth after professional oral hygiene

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Abstract

The article presents the results of electronic microscopic and X-ray spectral studies on the study of the surface microstructure and chemical composition of enamel and dentin during