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CLINICAL, PHARMACOTHERAPEUTIC AND BIORHYTHMOLOGICAL PECULIARITIES OF DEPRESSIVE DISORDERS, COMORBID WITH CARDIOVASCULAR PATHOLOGY

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The spread of depressive disorders is extra high nowadays. Among depressive disorders one can name depression and anxious disorders which affect somatic health and social well-being. Depressive disorders are the most widespread mental disorders among psychiatric pathology both causes of psychiatrist's visit and causes of medical aid [20]. According to WHO, the spread of anxious-depressive disorders equals to cardiovascular pathologies, so IHD is one of the most leading pathology, anxiety and depression occupy the 2nd one [3,12].

The presence of depressive syndrome in patients with cardiovascular diseases leads to deterioration of patient's life and adaptive abilities of patients, and aggravates somatic pathology. Recently, many hypotheses have been proposed of which biological mechanisms as a result to explain the development of depressive disorders [4,6]. For example, during somatic disease there are the following: decrease of the level of neurotransmitter in brain, weakening of immune system, depressive syndromes [1]. Depressive pathology in patients with somatic disorders causes the number of side effects both medical and social ones and reduces patient's life deterioration [7,13,17].

Patients with depression, hypertension is complicated by hypertensive crisis, that is often than in patients without depression. Depression which occurs after myocardial infarction in 3,5 times increases the risk of mortality [14,18]. So, adequate therapy of depression in 60-70% causes reduction, prevention of recurrent attacks and decompansation of comorbid somatic pathology, eliminates severe medical and prevents social consequences [21].

The study of clinical aspects of depressive conditions which present cardiac pathology is one of the main direction not only in psychiatric and also therapeutic, pharmacotherapeutic investigations [15,16].

The **aim** of the investigation was to determine clinical, pharmacotherapeutic and biorhythmological peculiarities of depressive disorders in patients with comorbid cardiac pathology. And also assessment of efficacy of complex therapy based on chronotherapy principle was used.

Material and methods. After obtaining the voluntary consent to participate in the study, a comprehensive survey of 50 patients (all women between the ages of 50 and 65) with depressive disorders undergoing inpatient treatment at the ME "Poltava Regional Clinical Psychiatric Hospital named after A. F. Maltsev of Poltava Regional Council" was carried out. The studies were conducted in compliance with the requirements of the Code of Ethics of the World Medical Association (the Declaration of Helsinki) and the Law of Ukraine "On Psychiatric Care" dated 02.22.2000 No. 1489-III.

The criterion for the inclusion of patients in the research was the presence of depressive syndrome in the framework of "Depressive disorder of organic genesis due to somatic pathology" (F 06.35), "Somatoform disorder" of the heart and cardiovascular system (F 45.30), "Mild depressive episode" (F 32.00) [5] as well as comorbid hypertension confirmed by a general practitioner, a cardiologist. Judging by the analysis of anamnestic data, the depressive syndrome was of a secondary nature, since the debut of manifestations of depressive disorder in the form of depressed mood (from two weeks or more), anhedonia, decreased energy and appetite, sleep disorders, decreased ability to concentrate, increased fatigue has manifested after establishing the diagnosis of grade I or II hypertension, stage 1-2 with medium risk.

The patients had not previously received antidepressant therapy and they all took drugs of the sartan (valsartan 80-160 mg) group 1 time per day as a part of antihypertensive therapy. All the examined patients, according to the research objectives, were divided into two equally numbered (25 people) clinical and diagnostic groups. Patients of group I received both antihypertensive and antidepressant therapy taking into account the individual chronotype, the type of individual chronotype was not taken into account in patients of group II and they received antihypertensive and antidepressant therapy daily at the same time (valsartan at 9-00 in the morning, mianserin at 8-00 in the evening reception). The choice of antidepressant therapy in favor of mianserin was made deliberately, taking into account the in-depth analysis of side effects regarding the activity of the cardiovascular system. They are minimal for this drug, while in other antidepressants they are more pronounced. Patients took mianserin at a dosage of 30 mg/day.

At the initial stage patients underwent a clinical-anamnestic, laboratory, clinical and psychopathological examination using psychodiagnostic scales (the Hamilton Rating Scale for Depression HAMD-21 and The Clinical Global Impression scales CGI-S, CGI-I were used to assess the severity of the patient's condition and evaluate the effectiveness of therapy) [11].

Chronodiagnostic measures were also carried out, which served as the basis for a system of further differentiated medical, therapeutic and preventive strategies. The main tasks of the chronodiagnostics were to determine the individual circadian chronotype of the patient (biorhythmological status). The main tasks of chronodiagnostics were to determine the individual circadian chronotype of the patient (biorhythmological status) by studying vegetative homeostasis (the dynamics of body temperature, pulse rate, systolic and diastolic blood pressure for 6 days every 3 hours). Taking into account the biorhythmological status of the patients, the morning-type individuals included those examined patients whose maxima of the studied functions occurred at 9-12 a.m., the evening-type individuals − at 6-9 p.m., and the indifferent individuals − at 12-3 p.m. Further, for all the studied patients according to the parameters that were investigated (body temperature, pulse rate, systolic and diastolic blood pressure), graphs were drawn based on the results of a six-day examination and their visual assessment was carried out. Biorhythmological diagnostics was performed by using a modified Estberg's questionnaire. The questionnaire consisted of 23 questions, each of which was evaluated by a certain number of points, depending on the rhythmological assessment of the subject's own performance. The sum of the obtained points was used to determine the chronobiological type of the patient: more than 92 points − clearly expressed morning type; 77-91 points − dimly expressed morning type; 58-76 points − indifferent type,

Table. The results of clinical and psychopathological studies in dynamics

	HAMD-21			CGI-S		CGI-I	
	before starting treatment	**after 2 weeks of therapy**	**after 4 weeks of therapy**	**before starting treatment**	**after 4 weeks of therapy**	**after 2 weeks of therapy**	**after 4 weeks of therapy**
Group I	15,46	10,26*	6,82*	4,43	1,65*	2,53*	1,48*
Group II	15,03	13,48*	9,86*	4,24	2,78*	3,63*	2,86*

*note: * $p<0.05$ – statistical reliability of the results*

42-57 points − dimly expressed evening type; below 41 points − a clearly expressed evening type [9]. The established individual biorhythmological status was taken into account when choosing the method of prescribing drug therapy, depending on the acrophase of the physiological (vegetative) parameter. The practical effectiveness of this approach is given in a number of modern scientific studies [2,8,10,19].

The results were analyzed and statistically processed using Excel in Microsoft Office 2010.

In clinical group I, antihypertensive and antidepressant therapy was prescribed taking into account the patient's biorhythmological status: patients with the morning chronotype were administered essential drugs with the distribution of the main dosage in the morning hours; drug therapy for the representatives of the indifferent circadian type was prescribed in the morning and afternoon hours; patients with the evening chronotype received the main drug dosage in the afternoon and evening hours.

In clinical group II, antihypertensive and antidepressant therapy was prescribed in the same volume, but without taking into account the individual circadian type.

Results and discussion. In both clinical groups, the indicators of the severity of depressive syndrome and the severity of the patient's condition were almost identical (the average score on the HAMD-21 scale was 15.46 in group I, 15.03 in group II, which corresponds to a mild depressive episode; the average score on the CGI-S scale was 4.43 in the first group and 4.24 in the second one, which corresponds to a mild degree of violation of the patient's condition).

In order to prevent erroneous or inaccurate interpretation of the treatment results, the therapeutic approach to the appointment of antidepressant therapy was reduced to monotherapy, all subjects were prescribed mianserin at a dose of 30 mg per day. Also, the patients received antihypertensive therapy under the supervision of the attending physician, general practitioner. The observation lasted 4 weeks.

A comprehensive assessment of the effectiveness of therapeutic measures was carried out by repeated psychodiagnostic examinations using the HAMD-21, CGI-S and CGI-I scales. The HAMD-21 scale was used for the initial assessment of the patient before taking the antidepressant (the initial indicator) in the second and fourth week of therapy. The CGI-I scale − at the 2nd and 4th weeks of treatment, CGI-S − before the start of treatment and after the 4th week of therapy.

According to the clinical observation of patients, analysis of the results of psychodiagnostic scales, the reduction of depressive symptoms in patients of group I (treated on the basis of the chronotherapy principle) occurred faster than in patients of group II, who received treatment without taking into account the circadian chronotype.

The reduction of the average indicators of depressive symptoms on the HAMD-21 scale in group I is as follows: the initial indicator is 15.46; the 2nd week is 10.26; the 4th week is 6.82 (which corresponds to a state without depression). Reduction of the average indicators of depressive symptoms on the HAMD-21 scale in group II: the initial indicator is 15.03; the 2nd week is 13.48; the 4th week is 9.86 (which corresponds to the presence of mild depression).

Significantly more indicative were the results in group I, demonstrating the severity of the condition on the CGI-S scale: before the start of treatment the average score was 4.43 (moderately severe condition), after 4 weeks of therapy − 1.65 (the condition is not impaired). In group II this indicator testified to the maintenance of the painful condition in the subjects: before treatment the average indicator was 4.24 (moderately severe condition), after 4 weeks of therapy − 2.78 (borderline state). In this group of patients there were indicators corresponding to the feeling of maintaining a mild course of the disease, which confirms the results on the HAMD-21 scale.

On the CGI-I scale assessing the therapy efficacy, the results of group I patients were also statistically significantly positive: at the 2nd week of therapy based on circadian compliance, the average indicator was 2.53, after 4 weeks of therapy −1.48. In patients of group II this indicator also showed an improvement in the state, but there was no significant improvement in their condition: at the 2nd week of therapy the average indicator was 3.63, after 4 weeks of therapy − 2.86. These results are presented in summary Table.

Conclusion. In the modern scientific literature, the drug treatment of anxiety-depressive disorders in patients with arterial hypertension is widely considered and the use of antidepressants with different chemical structure is analyzed [22]. However, works studying the treatment of hypertension comorbid with depressive disorders taking into account the individual biorhythmological status are rare, which gives clinical value to this study.

When comparing patients of the two study groups, it was found that in the group of patients who followed the principles of chronotherapy, namely antihypertensive and antidepressant therapy was prescribed taking into account the patient's biorhythmological status, the dynamics of improving the condition of patients in the form of reduction of depressive syndrome, more stable hemodynamic indicators was better than in the study group where the principle of chronotherapy was not observed. Maintenance of depressive symptoms creates unfavorable conditions and danger for decompensation of cardiac pathology and thereby for the patient's life.

Thus, comorbid mental affective pathology, namely depressive disorders, is a negative prognostic factor in patients with pathology of the cardiovascular system. The priority of antihypertensive therapy is undeniable. However, in the presence of concomitant depressive symptoms, neglecting to consult a psychiatrist to prescribe antidepressant therapy can delay treatment, impair its quality and thereby worsen the patient's quality of life.

The results of the studies have shown that a positive effect in the treatment of arterial hypertension, comorbid with manifestations of depression, is demonstrated by the complex use of antihypertensive therapy (drugs of the sartan group) with an antidepressant (mianserin) in accordance with the state of circadian rhythms of patients.

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SUMMARY

CLINICAL, PHARMACOTHERAPEUTIC AND BIORHYTHMOLOGICAL PECULIARITIES OF DEPRESSIVE DISORDERS, COMORBID WITH CARDIOVASCULAR PATHOLOGY

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The spread of depressive disorders is extra high nowadays. Depressive disorders are widespread mental disorders in the structure of mental pathology, both causes of psychiatrists' visit, and causes of medical aid. The presence of depressive syndrome in patients with cardiovascular system leads to deterioration patient's condition and adaptive abilities and aggravates somatic abnormality. Adequate therapy causes their reduction, prevention of recurrence and decompansation of comorbid somatic pathology, and eliminates severe medical and prevents social consequences. The study of clinical aspects of depressive conditions which are accompanied with pathology is one of the direction not only psychiatric, but also common pharmacotherapeutic investigations.

The aim of the investigation was to determine clinical, pharmacotherapeutic and biorhythmic peculiarities of depressive disorders in patients with comorbid cardiac pathology. And also

assessment of efficacy of complex therapy based on chronotherapy principle was used.

50 patients (female patients) with depressive disorders were involved in this investigation. This was performed based on “Depressive disorders of organic genesis, characterized by somatic pathology” (F 06.35), “Somatoform disorder” of heart and cardiovascular system (F 45.30), “Mild depressive episode” (F 32.00), and also comorbid arterial hypertension confirmed by physician. Clinical, laboratory, clinical and psychopathological investigations using psychodiagnostic scales (scale HAMD-21, CGI-S, CGI-I) were used. Individual biorhythmic status was established and it requires medicamentous therapy.

Comparing patients of both groups, it has been detected a group of patients in whom principles of chronotherapy, especially antihypertensive and antidepressive therapy were prescribed, dynamics of patient’s improvement was better than in the investigated group where the principle of chronotherapy was observed.

Keywords: depressive disorders, comorbidity, cardiac pathology, chronotherapy.

РЕЗЮМЕ

КЛИНИЧЕСКИЕ, ФАРМАКОТЕРАПЕВТИЧЕСКИЕ И БИОРИТМОЛОГИЧЕСКИЕ ОСОБЕННОСТИ ДЕПРЕССИВНЫХ РАССТРОЙСТВ, КОМОРБИДНЫХ С КАРДИАЛЬНОЙ ПАТОЛОГИЕЙ

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Показатели распространенности аффективных расстройств по сей день являются чрезвычайно высокими. Депрессивные расстройства – самые распространенные психические нарушения в структуре психической патологии, как среди причин обращения к психиатрам, так и среди всех причин обращения за медицинской помощью. Наличие депрессивного синдрома у пациентов с заболеваниями сердечно-сосудистой системы приводит к ухудшению качества жизни и адаптационных способностей больных, усугубляет течение соматической патологии. Адекватная терапия депрессий приводит к их редукции, предупреждению рецидивов психической патологии и декомпенсации коморбидной соматической патологии, устраняет тяжелые медицинские и предупреждает социальные последствия. Изучение клинических аспектов депрессивных состояний, которые сопровождают кардиальную патологию, остается и сегодня одним из главных направлений не только психиатрических, но и общемедицинских, фармакотерапевтических исследований.

Целью исследования явилось определение клинических, фармакотерапевтических и биоритмологических особенностей депрессивных расстройств у пациентов с коморбидной кардиальной патологией и оценка эффективности комплексной терапии, основанной на принципах хронотерапии.

Проведено комплексное обследование 50 женщин с депрессивными расстройствами в рамках «Депрессивного расстройства органического генеза, обусловленного соматической патологией» (F06.35), «Соматоформного расстройства» сердца и сердечно-сосудистой системы (F 45.30), «Легкого депрессивного эпизода» (F 32.00), а также коморбидной артериальной гипертензией, подтвержденной терапевтом. Проведено клинико-анамнестическое, лабораторное, клинико-психопатологическое обследование с использованием психодиагностических шкал - HAMD-21, CGI-S, CGI-I. Установленный индивидуальный биоритмологический статус учитывался при выборе способа назначения медикаментозной терапии в зависимости от акрофазы физиологического (вегетативного) параметра.

Сравнение результатов двух групп выявило, что в группе пациентов, в которой соблюдались принципы хронотерапии, в частности антигипертензивная и антидепрессивная терапия назначалась с учетом биоритмологического статуса пациента, динамика улучшения состояния пациентов в виде редукции депрессивного синдрома, более стабильных показателей гемодинамики была лучше, чем в группе, где принцип хронотерапии не соблюдался.

რეზიუმე

კარდიულ პათოლოგიასთან კომორბიდული დეპრესიული დარღვევების კლინიკური, ფარმაკოთერაპიული და ბიორიტმოლოგიური თავისებურებები

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[1]უკრაინის სამედიცინო სტომატოლოგიური აკადემია, ექსპერიმენტული და კლინიკური ფარმაკოლოგიის კათედრა კლინიკური იმუნოლოგიით და ალერგოლოგიით, პოლტავა; [2]პოლტავას ა.მალცევის სახელობის საოლქო კლინიკური ფსიქიატრიული საავადმყოფო, უკრაინა

კვლევის მიზანს წარმოადგენდა დეპრესიული დარღვევების კლინიკური, ფარმაკოთერაპიული და ბიორიტმოლოგიური თავისებურებების განსაზღვრა პაციენტებში კომორბიდული კარდიული პათოლოგიით და ქრონოთერაპიის პრინციპებზე დაფუძნებული კომპლექსური თერაპიის ეფექტურობის შეფასება.

ჩატარებულია 50 ქალის კომპლექსური კვლევა, რომელთაც აღენიშნებოდათ “სომატური პათოლოგიით გამოწვეული ორგანული გენეზის დეპრესიული დარღვევები” (F06.35), “გულის და გულ-სისხლძარღვთა სისტემის სომატოფორმული დარღვევები” (F45.30), “მსუბუქი დეპრესიული ეპიზოდი” (F32.00), ასევე, კომორბიდული არტერიული ჰიპერტენზია, დადასტურებული თერაპევტის მიერ. ჩატარებულია კლინიკურ-ანამნეზური, ლაბორატორიული, კლინიკურ-ფსიქოპათოლოგიური კვლევა ფსიქოდიაგნოსტიკური შკალების - HAMD-21, CGI-S, CGI-I გამოყენებით. მედიკამენტური თერაპიის შერჩევის დროს მხედველობაში მიიღებოდა დადგენილი ინდივიდური ბიორიტმოლოგიური სტატუსი ფიზიოლოგიური (ვეგეტატური) პარამეტრის აკროფაზისაგან დამოკიდებულებით.

ორი ჯგუფის შედეგების შედარების საფუძველზე გამოვლინდა, რომ პაციენტების ჯგუფში, რომელშიც გათვალისწინებული იყო ქრონოთერაპიის პრინციპები, კერძოდ – ანტიჰიპერტენზიული და ანტიდეპრესიული თერაპია ინიშნებოდა პაციენტის ბიორიტმოლოგიური

სტატუსის გათვალისწინებით, პაციენტების მდგომარეობის გაუმჯობესება დეპრესიული სინდრომის რედუქციის და ჰემოდინამიკის უფრო სტაბილური მაჩვენებლების სახით იყო უფრო მეტად გამოხატული, ვიდრე იმ ჯგუფში, სადაც ქრონოთერაპიის პრინციპი დაცული არ იყო.

ВЛИЯНИЕ КОМБИНИРОВАННОЙ ЭРАДИКАЦИОННОЙ И ПРОКИНЕТИЧЕСКОЙ ТЕРАПИИ НА КЛИНИЧЕСКИЕ ПРОЯВЛЕНИЯ, ПСИХОЛОГИЧЕСКИЙ СТАТУС И КАЧЕСТВО ЖИЗНИ ПАЦИЕНТОВ С ФУНКЦИОНАЛЬНОЙ ДИСПЕПСИЕЙ – ПОСТПРАНДИАЛЬНЫМ ДИСТРЕСС-СИНДРОМОМ: РАНДОМИЗИРОВАННОЕ ПРОСПЕКТИВНОЕ ИССЛЕДОВАНИЕ

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Диспепсия является наиболее частой причиной обращения за медицинской помощью к врачам общей практики – семейной медицины, терапевтам и гастроэнтерологам [1], существенно усиливая нагрузку на систему здравоохранения. Органическая природа диспепсических жалоб выявляется лишь в небольшом проценте случаев – около 30%, в то время как в 70% устанавливается диагноз функциональной диспепсии (ФД) [1,2].

Согласно современным представлениям, ФД имеет мультифакторную природу: нарушение опорожнения желудка, желудочной аккомодации, повышенная чувствительность желудка и двенадцатиперстной кишки (ДПК) к перерастяжению, кислоте и другим интралюминальным стимулам, повышенная проницаемость слизистой оболочки гастродуоденальной зоны, пищевые антигены, влияние внешней среды, воспаление ДПК низкой активности, психологические факторы, инфекция *Helicobacter pylori* [3].

По результатам кросс-секционного популяционного исследования среди 6300 жителей США, Канады и Великобритании, средние показатели распределения ФД по типам были следующими: постпрандиальный дистресс-синдром (ПДС) – 61%, эпигастральный болевой синдром (ЭБС) – 18%, вариант перекреста ПДС–ЭБС – 21%. Анализ распределения в этих странах выявил определенные различия, однако во всех трех странах наиболее частым типом ФД был ПДС (59% – в США, 63% – в Канаде, 63% – в Великобритании) [4].

Несмотря на высокий интерес к проблеме лечения ФД, стандартные подходы к ведению пациентов эффективны лишь в 15–30% случаев [5]. Актуальным является применение при ПДС прокинетиков, современный представитель которых – итоприда гидрохлорид (в Украине зарегистрирован под торговым названием «Мотоприд») – активирует и координирует пропульсивную моторику желудочно-кишечного тракта благодаря антагонизму к допаминовым D_2-рецепторам и ингибирующей активности ацетилхолинэстеразы. Препарат активирует высвобождение ацетилхолина и ингибирует его распад [6].

Вышеизложенное свидетельствует о необходимости дальнейшего глубокого и всестороннего изучения указанной проблемы.

Цель исследования - сравнительная оценка эффективности комбинированной эрадикационной и прокинетической терапии и только эрадикационной терапии в лечении функциональной диспепсии – постпрандиального дистресс-синдрома путем изучения их влияния на клинические проявления заболевания, психологический статус и качество жизни пациентов.

Материал и методы. Проведено рандомизированное проспективное исследование среди пациентов с ФД–ПДС. Набор пациентов проводился с апреля по декабрь 2020 г. на базе Коммунального некоммерческого предприятия «Киевский городской консультативно-диагностический центр» исполнительного органа Киевского городского совета (Киев, Украина). Исследование выполнено с соблюдением принципов Хельсинкской декларации и Гармонизированного руководства по надлежащей клинической практике (ICH E6(R2) GCP).

Критерии включения: возраст ≥18 лет; наличие функциональной диспепсии – постпрандиального дистресс-синдрома (ФД–ПДС) согласно критериям Римского консенсуса IV; наличие инфекции *Helicobacter pylori*; полное понимание характера исследования и предоставление письменного информированного согласия на участие в нем.

Критерии исключения: наличие органических, системных и/или метаболических заболеваний, которые могли объяснить наличие симптомов при осмотре или углубленном исследовании (включая эзофагогастродуоденоскопию); любой из следующих тревожных симптомов: начало симптомов в возрасте >45 лет, постоянная рвота, признаки кровотечения, железодефицитная анемия, семейный анамнез рака верхних отделов желудочно-кишечного тракта, прогрессирующая дисфагия и/или одинофагия; известная или возможная наркотическая и/или алкогольная зависимость; наличие сопутствующих заболеваний, требующих медикаментозного лечения.

В исследование включено 126 пациентов, разделенных на 2 исследуемые группы: I группа (основная) – 65 паци-