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METHODOLOGICAL APPROACHES TO THE FORMATION OF AN OPTIMAL RANGE OF ANTIDEPRESSANTS FOR THE INPATIENT TREATMENT OF MARTIAL LAW MENTAL DISORDERS

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Martial law in Ukraine has a negative impact on the mental health of the population. Even when a person is in relative safety, it does not provide a sense of complete comfort.

Today, the role of social and stressful factors is also growing significantly, including changes in professional and life stereotypes, difficulties in the material and domestic spheres related to the realities of the transition period in the development of society, and the inflation of previously stable social values.

Mental disorders occupy a significant place in the structure of the general morbidity rate, and a significant share of them (approximately 30%) is martial law mental disorders (MLD).

To optimise the provision of medicines for patients with martial law mental disorders, for the treatment of which antidepressants are mainly used, it is necessary to use optimal methods of pharmacotherapy, taking into account the effectiveness and safety of the medicines used.

The formation of an optimal range of antidepressants for the treatment of martial law mental disorders in a hospital setting is possible only if a deep and complete analysis of the wide range of antidepressants available on the modern pharmaceutical market is carried out. Research on optimising the development of an assortment of antidepressants for the inpatient treatment of martial law mental disorders has not received adequate attention. Thus, the development of methodological approaches to the formation of an optimal assortment of antidepressants for the inpatient treatment of martial law mental disorders is relevant.

The main medicines prescribed under the MHRA are antidepressants, which are represented by 18 international non-proprietary name and 37 trade names on the pharmaceutical market, and the use of which poses a number of difficulties, such as uncertainty of the course of treatment, polypharmacy, development of adverse drug reactions, and a number of others.

In order to identify the factors that influence the incidence of PWPS, and thus determine the supply and demand for antidepressants in the pharmaceutical market, the demographic and social characteristics of the population of patients with PWPS who underwent treatment were studied.

The results of the study of the contingent of patients with PWPS indicate that the incidence of martial law mental disorders tends to increase.

The analysis identified medicines whose procurement was stable in 2023.

The most frequently encountered combinations of psychotropic medications were identified and prescribed by doctors.

The mathematical models developed during the correlation and regression analysis made it possible to predict the need for drugs for the treatment of PWPS.

Key words: *pharmacoeconomic research, optimisation of pharmaceutical care, medicines, outpatient settings, inpatient treatment, martial law, mental disorders, range of medicines.*

Тетяна Негода, Жанна Полова. Методичні підходи до формування оптимального асортименту антидепресантів для стаціонарного лікування психічних розладів воєнного стану

Воєнний стан в Україні має негативний вплив на ментальне здоров'я населення. Навіть коли людина знаходиться у відносній безпеці, це не забезпечує відчуття повного комфорту.

Нині значно зростає ще й роль соціально-стресових чинників, зокрема зміни професійних і життєвих стереотипів, ускладнення у матеріальній і побутовій сферах, пов'язані з реаліями перехідного періоду в розвитку суспільства, інфляцією раніше стійких суспільних цінностей.

У структурі загальної захворюваності населення істотне місце посідають психічні розлади, а вагому частку серед них (приблизно 30%) – психічні розлади воєнного стану (ПРВС).

Для оптимізації лікарського забезпечення хворих на психічні розлади воєнного стану, для лікування яких використовують переважно антидепресанти, потрібне застосування оптимальних методів фармакотерапії з урахуванням ефективності та безпеки використовуваних лікарських засобів.

Формування оптимального асортименту антидепресантів для лікування психічних розладів воєнного стану в умовах стаціонару можливе лише за умови проведення глибокого і повного аналізу широкого асортименту антидепресантів, представлених на сучасному фармацевтичному ринку. Дослідженням, присвяченим оптимізації формування асортименту антидепресантів для стаціонарного лікування психічних розладів воєнного стану, не приділяли належної уваги. Таким чином, розроблення методичних підходів до формування оптимального асортименту антидепресантів для стаціонарного лікування психічних розладів воєнного стану є актуальним.

Основними лікарськими засобами, призначеними за ПРВС, є антидепресанти, які представлені 18 МНН і 37 торговими найменуваннями на фармацевтичному ринку, із застосуванням яких виникає низка труднощів, таких як невизначеність курсу лікування, поліпрагмазія, розвиток небажаних лікарських реакцій і низка інших.

Із метою виявлення чинників, що впливають на рівень захворюваності на ПРВС, а отже, визначають попит і пропозицію антидепресантів на фармацевтичному ринку, було вивчено демографічну та соціальну характеристику контингенту хворих на ПРВС, які проходили курс лікування.

Результати дослідження контингенту хворих на ПРВС свідчать про те, що захворюваність на психічні розлади воєнного стану має тенденцію до зростання.

Проведений аналіз виявив лікарські препарати, закупівля яких була стабільною упродовж 2023 р.

Було визначено комбінації психотропних лікарських засобів, які найчастіше траплялися і які призначали лікарі.

Складені під час кореляційно-регресійного аналізу математичні моделі дали змогу спрогнозувати потреби в препаратах для лікування ПРВС.

Ключові слова: фармакоекономічні дослідження, оптимізація фармацевтичної допомоги, лікарські засоби, амбулаторно-поліклінічні умови, стаціонарне лікування, воєнний стан, психічні розлади, асортимент лікарських засобів.

Introduction. Martial law in Ukraine has a negative impact on the mental health of the population. Even when a person is relatively safe, it does not provide a sense of complete comfort.

Today, the role of social and stressful factors is also growing significantly, including changes in professional and life stereotypes, difficulties in the material and domestic spheres associated with the realities of the transition period in the development of society, and the inflation of previously stable social values.

Mental disorders occupy a significant place in the structure of the total morbidity of the population, and a significant share of them (approximately 30%) is martial law mental disorders (MLD).

In today's market conditions and budgetary savings policy, the problem of inpatient drug provision for patients with socially significant diseases is urgent and requires scientifically based solutions using modern methods of pharmaceutical market research.

In order to optimise the provision of medicines to patients with martial law mental disorders, for the treatment of which antidepressants are mainly used as medicines, it is necessary to use optimal methods of pharmacotherapy, taking into account the effectiveness and safety of the medicines used.

The formation of an optimal assortment of antidepressants for the treatment of martial law mental disorders in an inpatient setting is possible only if a deep and complete analysis of the wide

range of antidepressants available on the modern pharmaceutical market is carried out. Research on optimising the development of an assortment of antidepressants for the inpatient treatment of martial law mental disorders has not received adequate attention. Thus, the development of methodological approaches to the formation of an optimal assortment of antidepressants for the inpatient treatment of martial law mental disorders is relevant.

Aims and objectives. To develop methodological approaches to the formation of an optimal range of antidepressants for the inpatient treatment of martial law mental disorders.

Research methods. The methodological basis of the study was the modern concept of marketing and pharmacoeconomic research of the medicines market [6], the methodology of system analysis [7], legislative and regulatory acts in the healthcare sector, and the results of our own research.

The study used the methods of retrospective, correlation and regression, comparative analysis, the method of collective expert assessment, etc. [8–11]

We analysed 600 medical records for the period of 2023, 30 questionnaires of pharmacists and 20 questionnaires of psychiatrists.

Results of the study. To study the market for medicines used to treat socially significant diseases, a set of marketing, pharmacoepidemiological, pharmacoeconomic analysis methods is currently used with a mandatory forecast of the need for

antidepressants. Mental disorders of martial law belong to a socially significant group of diseases that affect the quality of life of patients, significantly worsening all quality of life parameters, are difficult to diagnose, and the duration of treatment is not clearly defined in time. This is due to the absence of treatment standards as such, as well as the fact that the course of PWPS is difficult to determine.

Today, mental disorders occupy a leading position in the overall structure of morbidity, followed by cardiovascular diseases, and other diseases. According to the Center for Public Health, in 2020, the COVID-2019 pandemic resulted in a rapid increase in new cases of depressive disorders (53.2 million or 27.6%) and anxiety disorders (76.2 million or 25.6%).

According to the latest data from the Ministry of Health of Ukraine on the current state of morbidity and prevalence of mental disorders, the most common among all clinical groups is martial law mental disorders (MLD), which is a mental disorder that can develop after a traumatic event.

PWS manifests itself as a long-term reaction to stress – according to doctors, its manifestations appear 1–3 months after a traumatic event (in 75% of cases), but can also be observed after 4–6 months. It has also been confirmed that women aged 20–45 years are most likely to develop PWPS.

The following groups of symptoms are observed in PWPS: avoidance, hyperarousal, re-experiencing traumatic events, memory and emotional problems [1–5, 17].

The following manifestations are characteristic of PWPS:

- constant intrusive thoughts about the traumatic event;
- constant thoughts about their own safety, accompanied by the child's behaviour is marked by anxiety and agitation;
- avoiding references to the traumatic event;
- emotional emptiness;
- panic attacks;
- chronic pain, headaches, diarrhoea, feeling of tightness and burning behind the sternum, cramps, low back pain.
- distrust, the belief that the world is dangerous.
- alcohol, cigarette and drug abuse;
- destruction of relations with a partner;
- the emergence of suicidal thoughts.

The main medications prescribed for PWPS are antidepressants, which are represented by 18 INN and 37 trade names on the pharmaceutical market, and the use of which poses a number of difficulties, such as uncertainty of the course of treatment, polypharmacy,

development of adverse drug reactions, and a number of others [26–27].

Despite the specificity of this disease, the lack of specific methods and treatment courses makes it impossible to determine the need for antidepressants for inpatient treatment of PWPS by the regulatory method.

PWPS is treated with combination therapy, namely the use of pharmacotherapy and psychotherapy [3].

All of the above explains the difficulty of analysing and predicting the need for antidepressants used to treat PWPS, which are considered effective in inpatient settings.

In order to identify the factors that influence the incidence of PWPS, and therefore determine the supply and demand for antidepressants in the pharmaceutical market, the demographic and social characteristics of the contingent of patients with PWPS who underwent treatment were studied (Fig. 1).

The results of the study of the contingent of patients with PWPS indicate that the incidence of martial law mental disorders tends to increase.

Among all patients suffering from martial law mental disorders, the number of women prevails over men, and it should also be noted that martial law mental disorders are more common in urban areas than in rural areas.

Mental disorders of martial law are observed more often in patients aged 25–40 years.

Patients with PWPS are treated by psychiatric and neurological services.

Treatment of PWPS is mainly carried out in the inpatient setting.

Psychiatrists, who provide specialised care to patients with PWPS, are the end user, which affects the demand for this group of medicines.

Thus, we further investigated the system of inpatient drug provision.

The psychiatric service was financed from the state budget, as well as from patients' own funds and the voluntary health insurance fund.

The procurement of medicines for the hospital's needs is carried out by putting medicines out to open tender and electronic bidding (tender procurement).

In order to formulate an optimal range of antidepressants used for the treatment of PWPS, it is necessary to analyse the consumption of antidepressants.

The study used data on the procurement and expenditure of antidepressants for 2023. From 2022 to 2023, the main funds were spent on Zoloft (Sertralof) in a dosage of 50 mg.

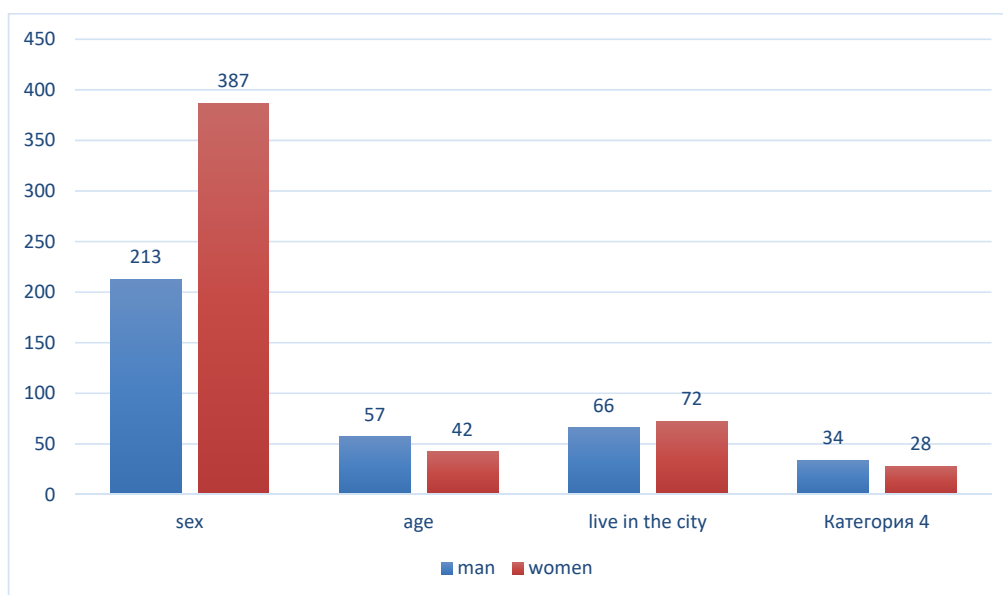


Fig. 1. Characteristics of the contingent of patients with mental disorders of military status

In 2023, the procurement volumes for the drugs presented were reduced, as drugs from other groups were procured, in particular, Mirtazapine in a dosage of 30 mg and Duloxetine in a dosage of 60 mg (which was mainly procured at the expense of consumers).

The study of the structure of antidepressant use in the treatment of PWPS was conducted at the next stage of the research.

An analysis of registration cards based on the medical records of patients treated in 2023 found that the frequency of prescribing Amitriptyline (21%) and Sertralofl (16%) to patients with depressive disorders was higher than that of other antidepressants. In most cases of psychotropic medication use, polytherapy was used.

In the treatment of martial law mental disorders, antidepressants were used in doses lower than the DDD (defined daily dose).

Further, 600 case histories for 2023 were studied to assess therapeutic efficacy. The calculations did not include the cost of treatment of adverse drug reactions observed during therapy with psychotropic medications (Table 1).

All the psychotropic medications studied were most often used in combination therapy with other psychotropic medications and in doses less than DDD.

The most commonly used combinations of psychotropic medications prescribed by doctors were identified.

Thus, the treatment of a severe depressive episode with amitriptyline had the best therapeutic effect. Monotherapy with “outdated” or traditional

psychotropic drugs was cheaper than therapy with new antidepressants and atypical neuroleptics.

The results of the analysis of the drug supply system (tender procurement) revealed problems with the choice of medicines required for tender procurement by distributors. The analysis of the antidepressant market found that in 2023, the pharmaceutical market for medicines included 16 international generic names and 35 brand names of antidepressants produced by 4 domestic, 29 foreign manufacturers and 2 jointly produced medicines.

In the pharmaceutical market, antidepressants are represented in a larger number by foreign manufacturers (76.92%).

This situation can be explained by the fact that from the very beginning, a greater number of companies involved in drug development were located abroad, as well as by the low funding of scientific research in Ukraine and the decline in the number of existing pharmaceutical plants. Another possible explanation may be the lack of need and the “imposition” by opinion leaders that everyone needs antidepressant treatment and the recommendation of imported drugs.

We have studied the number of trade names (generics) for each of the INN drugs.

It was found that the largest number of trade names is for Amitriptyline (7 trade names), Fluoxetine (9 trade names), Sertralofl (4 trade names), Clomipramine (2 trade names), Paroxetine (6 trade names). Other drugs have only one trade name each. It should be noted that the majority of antidepressants are original drugs or have virtually no generics. This indicates

Table 1

Combinations of psychotropic drugs used to treat a severe depressive episode. Economic analysis of psychotropic medicines (n = 600)

Drug combinations	DDD	Average daily doses of medicines	The course of treatment	The cost of a package of medicines	Cost of the treatment course (UAH)	Performance evaluation in points
Sertralofit	50 mg	0.5±0.07DDD	15 DDD	216,00	108,00	Effect
Sulpiride		0.5±0.03DDD	6 DDD	138,97	277,94	dubious
Quetiapine (n=61)		0.5±0.21DDD	15 DDD	261,3	261,3	
Amitriptyline (n=94)	75 mg	0.4±0.03DDD	8 DDD	63,6	127,2	The effect is achieved
Sertralofit (n=53)	50 mg		15 DDD	216,00	432,00	The effect is questionable
Amitriptyline	75 mg	0.4±0.02DDD	8 DDD	63,6	172,2	The effect is questionable
Risperidone (n=173)	8 mg	1,2±0,23DD	36 DDD	302,25	302,25	The effect is questionable
Amitriptyline	75 mg		8 DDD	63,6	172,2	The effect is achieved
Trifluoperazine (n=119)	100 mg	0.78±0.01DDD	23 DDD	36,00	36,00	achieved

a renewal of the antidepressant market, and rapid research work on the development and introduction of new antidepressants. Increased interest in this group of drugs indicates their demand and creates prospects for successful treatment of depression in the future. On the other hand, the increased number of trade names of antidepressants, rather than international generic names, suggests that this group of drugs brings large profits to manufacturers, as well as insufficient experience in the clinical use of antidepressants, which requires limiting the mass prescription of these drugs.

Among the dosage forms on the pharmaceutical market of antidepressants, oral dosage forms (tablets, capsules – Amitriptyline, Sertralofit, Clomipramine, Miacer, Mirtazapine, Cipramil, Fluoxetine, Fevarin, Paroxetine, Escitalopram, Venlafaxine) account for 77% of all dosage forms, parenteral dosage forms (ampoules, solutions for injection – Amitriptyline, Clomipramine) account for less than 23% of dosage forms.

The price lists of 10 leading wholesale pharmaceutical companies were used to analyse the antidepressant supplier market. Price list data for 3 months was used. The total number of offers in the price lists of antidepressants was 78 items.

The pharmaceutical market offers 16 international generic and 35 brand names of antidepressants produced by 4 domestic, 29 foreign manufacturers and 2 joint venture companies, which should be taken into account when selecting a supplier during tender procurement.

Taking into account that there are no standard methods of drug therapy for PWPS, no clearly defined courses of antidepressant treatment, and that antidepressants are used not only for the treatment of PWPS but are also widely used in the treatment of other diseases, it can be argued that the method of multivariate mathematical modelling is acceptable for obtaining a forecast of the need for antidepressants used to treat PWPS at the next stage of the study.

Correlation and regression analysis was used to determine the relationship between the factor and resultant attributes of the statistical population.

The needs for the main antidepressants were coded and labelled as “X”, the factors that influence them as “Y”.

The following factors have shown a correlation with the level of consumption of the studied drugs:

- the number of doctors, population size, number of beds,
- price increases, the incidence of male depression,
- the incidence of depression in women,
- the incidence of depression among the urban population,
- the incidence of depression among the rural population.

With an increase in the total number of patients with PWPS, the need for Amitriptyline 20mg 2.0 ml #10 increases. The correlation between the consumption of antidepressants and the increase in their prices is

either virtually absent (Saroten 50 mg 50 g=0.01) or has an average value (Zoloft 50 mg 28 g=0.5) The correlation coefficients are low, which indicates a weak dependence of the level of consumption on the prices of these drugs.

The mathematical models calculated for these drugs are presented in Table 2.

The obtained mathematical models can be used to assess the prospects for the need for drugs in the study group in case of different numerical values of the factors that affect the level of consumption of the study drugs (number of doctors, availability of beds, price levels for drugs in this group, etc.).

The mathematical models developed during the correlation and regression analysis made it possible to predict the need for drugs to treat PWPS.

When the coefficients of the equation were checked, the mathematical model of CipraleX proved to be unreliable.

Based on the data obtained, the growth trends for 2024 for Zoloft (SertralofT), CipraleX (Escitalopram),

Saroten (Amitriptyline), and Amitriptyline (Amitriptyline) were identified.

The demand for Amitriptyline in ampoules and tablets will decrease due to the market demand for medicines in a convenient dosage form, such as tablets.

Thus, the established correlation and regression equations made it possible to predict the need for antidepressants for inpatient treatment.

Conclusions. The results of pharmacoepidemiological studies of morbidity and methods of marketing research of the market of antidepressants used for inpatient treatment of PWPS make it possible to develop methodological approaches to the formation of an optimal range of antidepressants for inpatient treatment of PWPS, which could be a scientifically sound solution to the problem of providing antidepressants to patients with PWPS in a hospital setting. However, the work may be incomplete if we do not take into account the problem of choosing medicines in the context of tender procurement.

Table 2

Mathematical models of the need for antidepressants used in the treatment of PWPS and assessment of their reliability

Antidepressant	Type of mathematical model	F – Fisher's criteria		Satisfied. «+» Nedostov. «-»
		Calculation.	Table.	
Amitriptyline 20mg2ml#10amp (Amitriptyline)	$XI = -285.59808 * Y1 + 713.20376 * Y2 - 202.77638 * Y4 - 40.71873 * Y6 + 2974.81260 * Y7 - 104.42655 * Y92 - 33.08307 * Y95 + 151299.548$	4,73	6,39	+
Zoloft 50mg #28 (SertralofT)	$X2 = 683.21992 * Y2 - 2660.65081 * Y6 - 876,08880 * Y95 + 7122196,06602$	5,16	6,39	+
Coaxil 12,5 mg # 30 (Tianeptine)	$XZ = -135.41474 * Y92 + 215582,05877$	6,17	6,39	+
Saroten 50mg #50 (Amitriptyline)	$X4 = -496.84863 * Y91 + 44721.78776$	5,96	6,39	+
CipraleX 20mg #28 (Escitalopram)	$X5 = 39108759,23108 * Y5 - 20789804,73529 * Y91 + 82255934,57412$	13,55	6,39	-
Amitriptyline 25mg #50 (Amitriptyline)	$X6 = 24.70315335 * Y6 + 375.3361121 * Y7 + 6.130822657 * Y97 + 114.113 8244 * Y93 + 17.24847972 * Y94 + 2.703811718 * Y95 - 119706.8861$	4,27	6,39	+
CipraleX 10mg #28 (Escitalopram)	$X7 = -13029.90075 * Y1 + 110055.7228 * Y2 + 15136 * Y3 - 6492.526612 * Y4 - 98060.09112 * Y7 - 9835.344472 * Y93 + 518.7117523 * Y94 + 6029050.95$	5,84	6,39	+

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