МІНІСТЕРСТВО ОХОРОНИ ЗДОРОВ'Я УКРАЇНИ
ДЕРЖАВНИЙ ЕКСПЕРТНИЙ ЦЕНТР МОЗ УКРАЇНИ
НАЦІОНАЛЬНИЙ ФАРМАЦЕВТИЧНИЙ УНІВЕРСИТЕТ

Рік заснування – 1997

Назустріч VIII Національному з'їзду фармацевтів України

КЛІНІЧНА ФАРМАЦІЯ

CLINICAL PHARMACY

КЛИНИЧЕСКАЯ ФАРМАЦИЯ

2016 – том 20, № 2

Харків
НФаУ

У черговому номері журналу представлені матеріали VIII науково-практичної конференції «Фармакоекономіка в Україні: стан та перспективи розвитку», яка була проведена на базі Національного фармацевтичного університету (м. Харків) 26-27 листопада 2015 р. У публікаціях наведені результати фармакоекономічних та фармакоепідеміологічних досліджень, аналізу якості фармакотерапії захворювань у закладах охорони здоров'я України, висвітлена роль інформаційних технологій в забезпеченні якості фармацевтичної допомоги, також представлені результати впровадження формулярної системи та медичних стандартів в Україні, аналізу фармакотерапевтичних груп на українському фармацевтичному ринку, розглянуті методичні підходи до підготовки провізорів та лікарів, управлінські аспекти діяльності фармацевтичної галузі.

Для науковців, лікарів, провізорів, клінічних провізорів, організаторів системи охорони здоров'я.

Рекомендовано Вченою радою Національного фармацевтичного університету
(протокол № 9 від 31.05.2016 р.)

Журнал "Клінічна фармація" включений до затвердженого МОН України переліку наукових фахових видань України для опублікування результатів дисертаційних робіт з фармацевтичних та медичних наук (Наказом Міністерства освіти і науки України №793 від 04.07.2014 р. поновлений в Переліку наукових фахових видань України, в яких можуть публікуватися результати дисертаційних робіт на здобуття наукових ступенів доктора і кандидата наук)

Журнал «Клінічна фармація» входить у реферативну базу даних Національної бібліотеки України ім. В.І.Вернадського, Українського реферативного журналу «Джерело», Chemical Abstracts Service (USA), ВИНИТИ РАН та включений до наукометричної бази eLIBRARY.RU.

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Назустріч VIII Національному з'їзду фармацевтів України

VIII НАЦІОНАЛЬНИЙ З'ЇЗД ФАРМАЦЕВТІВ УКРАЇНИ
13-16 вересня 2016 року, м. Харків

ІНФОРМАЦІЙНЕ ПОВІДОМЛЕННЯ

Організатори з'їзду:

- Міністерство охорони здоров'я України;
- Міністерство освіти і науки України;
- Національна академія наук України;
- Національна академія медичних наук України;
- Громадська організація «Всеукраїнська фармацевтична палата»;
- Харківська обласна державна адміністрація;
- Харківська обласна рада;
- Харківська міська рада;
- Громадська організація «Харківська обласна асоціація фармацевтичних працівників»;
- Державна служба України з лікарських засобів;
- Національний фармацевтичний університет

Шановні колеги!

Організаційний комітет запрошує Вас взяти участь у роботі VIII Національного з'їзду фармацевтів України, який відбудеться **13-16 вересня 2016 року** у м. Харкові на базі Національного фармацевтичного університету (посвідчення УкрІНТЕІ № 113 від 21.04.2015 р.).

У рамках проведення з'їзду відбудеться **науково-практична конференція «Фармація XXI століття: тенденції та перспективи»**.

Мета з'їзду: підведення підсумків, обговорення та затвердження концепції розвитку фармацевтичного сектора галузі охорони здоров'я України на 2016-2021 рр.

Робочі мови з'їзду: українська, англійська, російська.

Делегати з'їзду обираються на регіональних конференціях згідно з Положенням і квотами, затвердженими Міністерством охорони здоров'я України та Фармацевтичною асоціацією України. Конференції щодо вибору делегатів проводяться регіональними асоціаціями фармацевтичних працівників до 1 червня 2016 року.

ОРІЄНТОВНА ПРОГРАМА З'ЇЗДУ

13 вересня 2016 року – реєстрація делегатів та учасників з'їзду, спонсорів, партнерів.

14 вересня 2016 року – урочисте відкриття VIII Національного з'їзду фармацевтів України, пленарні засідання, обговорення концепції розвитку фармацевтичного сектора галузі охорони здоров'я України на 2016-2021 рр.

15-16 вересня 2016 року – науково-практична конференція «Фармація XXI століття: тенденції та перспективи»: наукові симпозіуми, лекції майстер-класу, круглі столи, воркшопи, дискусії.

Організаційний внесок для одного делегата/учасника складає 995 грн (без ПДВ).

Організаційний внесок не передбачає оплати за проживання, але організаційний комітет зобов'язується розселити учасників з'їзду, якщо у реєстраційній формі Вами буде зроблена заявка. Інформація щодо проживання у готелях розміщена на сторінці з'їзду на сайті НФаУ.

Особи, які не є делегатами з'їзду, можуть взяти участь у його роботі (без права голосування) за умови сплати організаційного внеску. Їм гарантується участь у всіх заходах і отримання матеріалів нарівні з делегатами з'їзду.

Організаційний внесок гарантує: участь у пленарних засіданнях і науково-практичній конференції; одержання інформаційних і робочих матеріалів з'їзду; одержання делегатського кейсу; одержання ексклюзивних видань, підготовлених до VIII Національного з'їзду фармацевтів України; присутність на концертній програмі; участь у фуршетах під час роботи з'їзду; одержання сертифікату учасника з'їзду; участь в екскурсійній програмі; транспортні послуги.

Для участі тільки у **науково-практичній конференції «Фармація XXI століття: тенденції та перспективи» організаційний внесок для одного делегата складає** 400 грн (без ПДВ), що гарантує одержання інформаційних матеріалів VIII Національного з'їзду фармацевтів України, участь у роботі секційних засідань, наукових симпозіумів, круглих столів, лекціях майстер-класу, воркшопах, а також публікацію тез доповідей, одержання сертифікату учасника науково-практичної конференції.

Симпозіуми науково-практичної конференції

- Конструювання, синтез і модифікація біологічно активних сполук та створення на їх основі лікарських субстанцій.
- Сучасні підходи до створення нових лікарських та косметичних засобів, дієтичних добавок природного походження.

- Сучасний фармацевтичний аналіз та стандартизація ліків.
- Актуальні проблеми сучасної технології ліків, екстемпоральної рецептури, пакування та маркування лікарських препаратів.
- Сучасні аспекти розробки та промислового виробництва фармацевтичних препаратів. Біотехнології та нанотехнології у фармації.
- Механізми патологічних процесів та їх фармакологічна корекція.
- Клінічна фармація: від експериментальної розробки лікарських засобів до стандартизації фармацевтичної допомоги.
- Соціальна фармація: стан, проблеми та перспективи.
- Фармацевтична освіта в Україні.
- Фармація молода.

Публікація матеріалів

Матеріали науково-практичної конференції будуть опубліковані у збірнику матеріалів VIII Національного з'їзду фармацевтів України.

Текст повідомлення (одна повна або дві повні сторінки) друкується на аркуші формату А4 (ширина полів: ліве, праве, верхнє – по 2 см, нижнє – 3 см); шрифт Times New Roman, розмір шрифту – 12, інтервал – 1,1. Прохання дотримуватися наведеної структури:

Зверху по центру без відступу першого рядка:

НАЗВА ПОВІДОМЛЕННЯ ВЕЛИКИМИ ЛІТЕРАМИ (жирним шрифтом);

прізвище та ініціали авторів; якщо автор або один із співавторів повідомлення планує виступити на конференції з доповіддю, його прізвище слід підкреслити;

назва організації/наукової установи.

Через рядок друкується основний текст повідомлення (абзацний відступ – 1,25 см; вирівнювання по ширині, автоматичне розставляння переносів).

Усі матеріали подаються у 2-х примірниках і супроводжуються направленням від організації, в якій виконано роботу, експертним висновком, що дозволяє відкриту публікацію, та копією квитанції про оплату публікації матеріалів (або участь у з'їзді чи конференції). Другий примірник підписується всіма авторами. До друкованого варіанту матеріалів додається електронна копія – файл, виконаний у редакторі MS Word з розширенням RTF. Кожне повідомлення оформляється у вигляді окремого файлу, названого за прізвищем першого автора (якщо автор подає більше однієї роботи, до прізвища додається її порядковий номер). Файли слід надсилати разом з паперовим варіантом або електронною поштою доданим файлом, обов'язково вказуючи у темі повідомлення «Тези».

Оплата за публікацію однієї сторінки матеріалів складає 100 грн (без ПДВ).

Особи, які сплатили організаційний внесок за участь у з'їзді або науковій конференції, звільняються від оплати за публікацію матеріалів.

Матеріали мають бути надіслані **не пізніше 1 липня 2016 року** на адресу: 61002, м. Харків, вул. Пушкінська, 53, науковий відділ НФаУ, контактний телефон/факс: (057) 706-30-71, E-mail: conference_nauka@nuph.edu.ua *(обов'язково вказувати у темі повідомлення «Тези»).*

До уваги учасників!

Банківські реквізити для оплати:

Отримувач:

Громадська організація «Харківська обласна асоціація фармацевтичних працівників»

ГО «ХОАФП», 61013, м. Харків, вул. Челюскінцев, 3.

ідентифікаційний код ЄДРПОУ 33481466

ХАРКІВ. ГРУ ПАТ КБ»ПРИВАТБАНК», м. ХАРКІВ

р/р 26003060383169, МФО 351533

Призначення платежу:

- Сплата організаційного внеску за участь у VIII Національному з'їзді фармацевтів України від (прізвище, ініціали) згідно з інформаційним повідомленням, 995 грн (без ПДВ).
- Сплата організаційного внеску за участь у науково-практичній конференції від (прізвище, ініціали) згідно з інформаційним повідомленням, 400 грн (без ПДВ).
- Сплата за публікацію тез доповідей від (прізвище, ініціали) згідно з інформаційним повідомленням (без ПДВ);
- Благодійний внесок згідно з інформаційним повідомленням.

ІНФОРМАЦІЯ ДЛЯ СПОНСОРІВ

З питань надання благодійної допомоги звертатися до відповідального секретаря VIII Національного з'їзду фармацевтів України.

Преференції спонсорам: можливість розповсюдження рекламної продукції фірми разом з інформаційними та робочими матеріалами з'їзду; розміщення логотипу спонсора на банерах та в усіх виданнях VIII Національного з'їзду фармацевтів України; можливість організації сателітних симпозіумів та освітніх заходів; участь у всіх заходах і отримання матеріалів з'їзду.

Реєстрація делегатів/учасників проводиться також і в on-line режимі на сайті НФаУ: nuph.edu.ua в розділі «Назустріч VIII Національному з`їзду фармацевтів України».

ОРГКОМІТЕТ VIII НАЦІОНАЛЬНОГО З'ЇЗДУ ФАРМАЦЕВТІВ УКРАЇНИ

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Фармакоекономіка

UDC 615.1/3

PHARMACOEPIDEMIOLOGICAL ANALYSIS: DYNAMICS OF AVAILABILITY OF STATINS IN UKRAINE

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National University of Pharmacy

Key words: pharmacoeconomics; statins; pharmaceutical market; range of drugs; dynamics; coefficient of the solvency adequacy

Diseases of the circulatory system are the main cause of disability and premature death in Ukraine. A great number of RCTs and meta-analyses proved high preventive efficiency of statins to reduce the cardiovascular risk. The aim of the study is to analyze the dynamics of cost and availability of statin drugs in Ukraine in 2012-2015. Dynamics of the prices for some statin drugs was determined according to the data of the "Pharmstandard" system of "Morion" company. To assess availability of the statin therapy the coefficient of the solvency adequacy was used. According to the results of the study it has been found that at the pharmaceutical market of Ukraine there is an adequate range of statin drugs. During the period from 2012 to 2015 there was the positive dynamics of the market structure – increase in domestic drug production and its share in the market structure. From 2014 there was the increase in prices for the vast majority of drugs of the statin group of both domestic and foreign production – the average for the group was 42.1% and 101.4%, respectively. The dynamics of the solvency adequacy indicates decrease in availability of statin drugs for the Ukrainian consumers in the period from 2012 to 2015. Under these conditions the possibility of the primary and secondary prevention of CVD is provided by high economic availability of domestic generic drugs, which range over the past four years has increased by 38%. Measures in the healthcare system, contributing to increase availability and the amounts of statin use in Ukraine are needed.

Diseases of the circulatory system are the main cause of disability and premature death all over the world. In Ukraine the number of deaths from diseases of the circulatory system, including coronary heart disease (CHD) and stroke, exceeded the number of deaths of all types of cancer, AIDS and tuberculosis taken together in 2012 [1, 2]. In 2014 the death rate from the circulatory system diseases was 676 persons per 100 000 of the population. It is one of the highest rates in Europe [3].

The numerous epidemiological studies proved the role of hypercholesterolemia in morbidity and mortality of coronary heart disease [27, 32] and stroke [4, 9] over the last decade. The benefits of lipid reduction in the coronary artery disease were demonstrated in meta-analyses of the prospective controlled clinical trials concerning reduction of cholesterol; they included 65.000 patients who took the statin group of drugs [10, 22]. The meta-analysis of 24 published trials of the comparative statin therapy with the control group, which included 165,792 persons, demonstrated that the statin therapy was associated with reduction in frequency of all strokes – primary and repeated, ischemic and hemorrhagic ones – approximately by one-fifth [9, 16]. These data formed the basis for application of the statin therapy as the primary strategy for reducing the risk of cardiovascular complications [4, 14, 17]. The number of meta-analyses of the studies with statins included more than 170.000 cases and indicated the safety of therapy if these medicines were used [23, 24, 31]. The clinical studies of the past recent years confirm the high efficiency and safety of the statin therapy for patients with the risk factors [12, 13, 26, 28]. The positive effect of statins on the vascular state, which was not related to the effect on the lipid level, was also proven [11, 29]. Taking into account the high morbidity and mortality the primary and secondary statin prevention is indicated for the significant segment of the population of Ukraine.

The real possibility of using statins in the clinical practice depends largely on availability of the appropriate drugs at the pharmaceutical market, their product range and affordability for the general population.

The aim of the work was to analyze the dynamics of the cost and economic availability of drugs of the statin group in Ukraine in 2012-2015.

Materials and Methods

Such research methods as logical, monitoring, system, and graphic were used. The analysis of the range and cost of domestic and foreign statin drugs was conducted on the basis of the data of the "Pharmstandard" system of "Morion" company [7]. The data on average wages were taken from the official website of the State Statistics Committee of Ukraine [3]. To assess economic availability of the statin therapy for the Ukrainian population the coefficient of the solvency adequacy was used. It shows the percentage of the average wage accounts for the cost of a course of treatment by a

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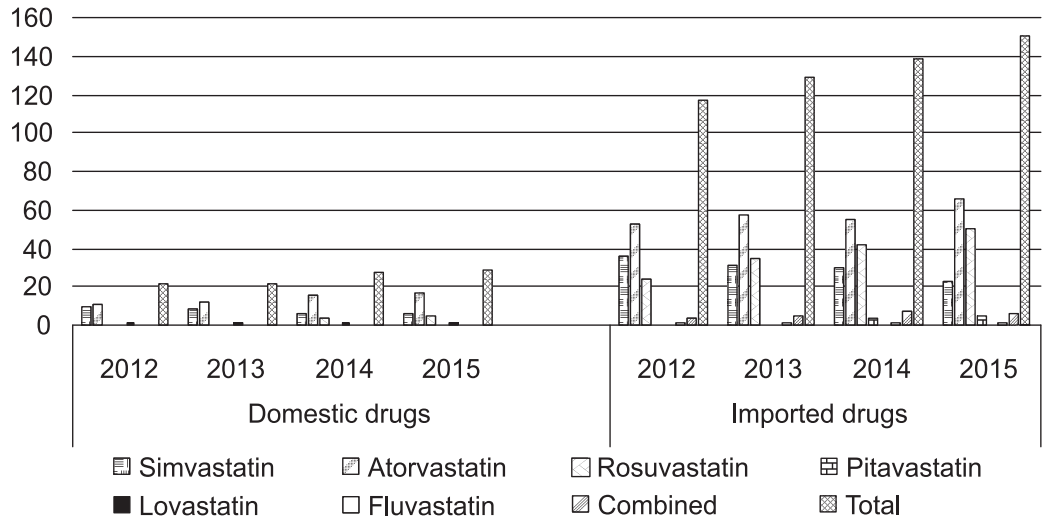

Fig. 1. The range of statin drugs at the Ukrainian pharmaceutical market in 2012-2015

specific drug and the solvency of the consumer. The lower the value of this indicator is, the greater availability of the drug is for the consumer [5, 6]. This indicator was calculated only for those drugs, which were present at the market during the period of study, according to the formula:

$$Ca.s. = (Pav/Wa.w.) \times 100\%,$$

where: Ca.s. – is the coefficient of the solvency adequacy;
Pav – is the average cost of a course of treatment by the drug for a certain period;
Wa.w. – is the average wage for a certain period.

The cost of one month of the treatment by each of the statins in the dose equal to DDD was taken as the cost of the course of treatment in this study. DDD is the standard average daily dose of the drug used according to the main indications in adults [15, 25]. DDD is as close as possible for the actual application and is derived on the basis of practical recommendations and reference sources, as well as the clinical experience of the drug use [18]. Calculating the cost of treatment using DDD allows to estimate approximately the real costs for drug treatment [8].

Results and Discussion

As of December 2015, taking into account the unit doses and dosage forms, at the Ukrainian pharmaceutical market there were 180 statin drugs (29 domestic and 151 imported ones) from 49 manufacturers (13 domestic and 36 foreign producers). From 2012 to 2015 the number of drugs of the statin group increased by 30.4%. The range of the domestic drugs was greater than import ones (38% and 29%, respectively). Such drugs as atorvastin and rosuvastatin by two domestic producers were added to simvastatin and lovastatin available at the drug market. Nevertheless, the percentage of statins in the structure of the domestic market remains significantly less than the import drugs (16.1% and 73.9%, respectively). The largest growth of the range of drugs was recorded for rosuvastatin (129%). The range of drugs of atorvastatin increased by 29.6%, while simvastatin decreased by 35.6% (Fig. 1). In the randomized clinical trials conducted and the meta-analyses generalizing them it has been shown that by efficiency of reduction of CHD statins are divided in descending order as follows: rosuvastatin – atorvastatin – simvastatin [19, 20, 21, 30]. In our opinion, the dynamics of the statin range at the Ukrainian pharmaceutical market should be assessed as positive.

Thus, the analysis carried out has indicated that statin drugs at the Ukrainian pharmaceutical market are presented in the sufficient range. During the period from 2012 to 2015 there was the positive dynamics of statin drugs: increase in domestic drug production and its share in the market structure, appearance of new domestic manufacturers of statins, the share increase of rosuvastatin drugs. Rosuvastatin is newer than simvastatin and atorvastatin with the proven efficacy and safety as a hypolipidemic drug.

In addition to the physical accessibility of drugs, the real possibility of pharmacotherapy to a large extent depends on their economic availability. The analysis of the dynamics of the prices for statin drugs indicated the following advantages. In 2013 as compared to 2012 there was 12-14% increase in price for 55% of domestic simvastatins, while the price for 44.6% of drugs became lower by 1.4-6.3%. In 2014 the price reduction was for 3 of 10 domestic simvastatin drugs presented at the Ukrainian market. In 2015 these drugs were not presented at the market. The prices for all domestic simvastatin drugs left at the market in 2015 as compared to 2014 increased by 2.7-41.3%. In general, over the period of 2012-2015 domestic simvastatins became more expensive by 33%.

During the period analyzed the prices for domestic drugs of ator-

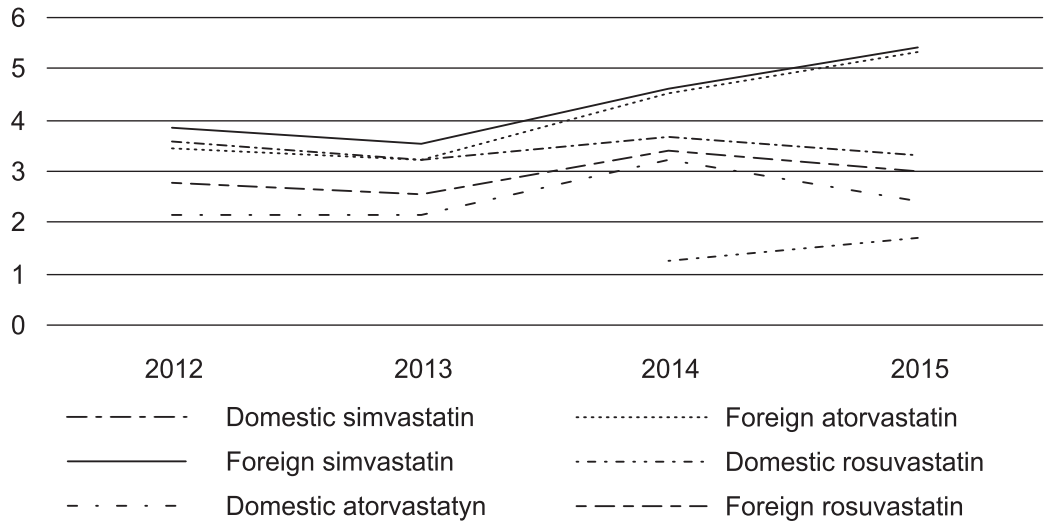

Fig. 2. The dynamics of the coefficient of the solvency adequacy (Ca.s) for statin drugs in the period from 2012 to 2015

vastatin have a clear tendency to increase: in 2013 from 2.5 to 25.8%, in 2014 from 7.6 to 63.8%, in 2015 from 10.2 to 30.0%. Only one domestic atorvastatin drug (Vasocleen, film coated tablets, 20 mg, No.30, produced by "Darnitsa" JSC) reduced the price by 32% in 2015. In general, from 2012 to 2015 domestic drugs of atorvastatin became more expensive approximately by 43.9%. The domestic rosuvastatin appeared at the market in 2014 and was presented only by four trade names of one manufacturer. In 2015 the price for these drugs increased from 29.4 to 104.9%. In general, from 2012 – 2015 the prices for domestic statins increased on average by 42.1%.

A clear trend to increase the average prices and the number of drugs, which price increases every year, is observed in the analysis of the market of statin drugs of foreign production. For example, in 2013 the price dropped from 0.5 to 11.3% for 37.5% of simvastatin drugs, 30.0% of atorvastatin drugs and 21.4% of rosuvastatin drugs. In 2014 the price dropped within 0.3-6% for 6 drugs of simvastatin (20.7% of the range), and only for one drug of atorvastatin and 2 drugs of rosuvastatin. The price increased in the vast majority of drugs of the statin group of the foreign production in 2014, and it was significantly high for the statin group by 32%, and for the number of medicines there was increase by 60% and even by 80%. In 2015 the price for the most of the drugs mentioned had further increase (for 94.7% of simvastatin drugs, 81.8% of atorvastatin drugs and 85.7% of rosuvastatin drugs); it was more significant than in 2014 – 49.4%. For the period of 2012-2015 the prices for statins of the foreign production grew by 101.4%. It is almost 2.5 times higher than the prices for domestic products.

One of the main causes for increase in prices for medicines, as well as other products, was the growth rate of the U.S. dollar starting in mid-2014, and it continues to the present day. In addition, the sales of the domestic products occur mostly by one-two-level marketing channels in contrast with foreign drugs, which are promoted by means of the multi-level distribution channels. However, despite the dependence on the dollar rate the rise in the price of the absolute majority of the foreign statin drugs was behind the changes of the exchange rate. Only for 6 drugs (3% of the range) the price was the same and even slightly exceeded the dollar rate increase.

The price of the medicine, of course, significantly affects its availability, but the coefficient of the solvency adequacy (Ca.s) gives more complete idea of the possibility of using one or another drug in clinical practice. The low value of this coefficient provides the drug availability and guarantees its sales in low solvency of the population [2, 5, 6].

The dynamics of Ca.s for statin drugs in the period from 2012 to 2015 is given in Fig. 2 and Table. The slight decrease of the value of Ca.s of 2013 for all INN statins changed by its rise in 2014, and it reduced the availability of statin drugs for the general population. In 2015 availability of foreign drugs of simvastatin and atorvastatin became even smaller. It was indicated by increase of the value of Ca.s. For the domestic drugs of simvastatin and atorvastatin, and import drugs of rosuvastatin the value of Ca.s decreased as compared to 2014, but did not reach the level of 2013. Despite the negative dynamics of the coefficient of the solvency adequacy all domestic statin drugs without exception remain highly available to the consumer until now (Table).

With the high probability it can be assumed that increase in the price of drugs and increase of the coefficient of the solvency adequacy can lead to reduction of the consumption of statin drugs. This, in turn, will reduce the possibilities of the primary and secondary prevention and create conditions for increasing the probability of cardiovascular accidents in patients

Table

Distribution of statin drugs in accordance with the categories of availability by the coefficient of the solvency adequacy

MNN	Manufacturer	Categories of availability	2012 (%)	2013 (%)	2014 (%)	2015 (%)
Simvastatin	domestic	highly available Ca.s < 5%	77.8	100	100	100
		medium available < 5%Ca.s < 15%	22.2			
	import	highly available Ca.s < 5%	69.4	80.0	60.7	61.9
		medium available < 5%Ca.s < 15%	30.6	20.0	39.3	38.1
Atorvastatin	domestic	highly available Ca.s < 5%	100.0	100.0	100.0	100.0
	import	Ca.s < 5%	90.7	91.5	80.0	69.7
		medium available < 5%Ca.s < 15%	7.0	6.4	16.0	24.2
		low available Ca.s > 15%	2.3	2.1	4.0	6.1
Rosuvastatin	domestic	highly available Ca.s < 5%			100.0	100.0
	import	highly available Ca.s < 5%	89.3	91.7	83.7	90.0
		medium available < 5%Ca.s < 15%	10.7	8.3	16.3	10.0

with the risk factors, resulting in the increased morbidity and cardiovascular mortality. The research in this area is expedient to proceed.

CONCLUSIONS

1. There is an adequate range of statin drugs at the pharmaceutical market of Ukraine. During the period from 2012 to 2015 there was the positive dynamics of the market structure – increase in domestic drug production and its share in the market structure, appearance of new domestic manufacturers of statins.

2. Since 2014 there was increase in prices for the vast majority of drugs of the statin group of both domestic and foreign production – the average for the group was 42.1% and 101.4%, respectively.

3. The dynamics of the coefficient of the solvency adequacy indicates decrease in availability of statin drugs for the Ukrainian consumers in the period from 2012 to 2015. Under these conditions the possibility of the primary and secondary prevention of CVD is provided by high economic availability of domestic generic drugs, which range over the past four years has increased by 38%. Measures in the healthcare system, contributing to increase availability and the amounts of statin use in Ukraine are needed.

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ФАРМАКОЕПІДЕМІОЛОГІЧНИЙ АНАЛІЗ: ДИНАМІКА ДОСТУПНОСТІ СТАТИНІВ В УКРАЇНІ

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Ключові слова: фармакоекономіка; статини; фармацевтичний ринок; асортимент лікарських препаратів; динаміка; коефіцієнт адекватності платоспроможності

Захворювання системи кровообігу – основна причина інвалідності та передчасної смерті в Україні. Великою кількістю РКД та мета-аналізів доведена висока профілактична ефективність застосування статинів для зниження ризику серцево-судинних захворювань (ССЗ). Мета дослідження – аналіз динаміки вартості і економічної доступності лікарських препаратів статинів в Україні за період 2012-2015 рр. Динаміку цін на окремі препарати статинів визначали за даними системи «Фармакостандарт» компанії «Моріон». Для оцінки економічної доступності статинотерапії використовували показник адекватності платоспроможності. За результатами дослідження визначено, що на фармацевтичному ринку України представлений достатній асортимент лікарських препаратів статинів. За період з 2012 р. по 2015 р. відзначається позитивна динаміка структури ринку – збільшення ЛП вітчизняного виробництва та їх частки в структурі ринку. З 2014 р. відзначається зростання цін для абсолютної більшості лікарських препаратів групи статинів як вітчизняного, так і зарубіжного виробництва – в середньому по групі на 42,1% і 101,4% відповідно. Динаміка показника адекватності платоспроможності свідчить про зменшення економічної доступності препаратів статинів для українського споживача в період з 2012 р. по 2015 р. При цих умовах можливість первинної та вторинної статинопрофілактики ССЗ забезпечується високою економічною доступністю вітчизняних генеричних препаратів, асортимент яких за останні чотири роки виріс на 38%. Потрібні заходи у системі охорони здоров'я, які б сприяли підвищенню доступності та об'ємів споживання статинів в Україні.

ФАРМАКОЭПИДЕМИОЛОГИЧЕСКИЙ АНАЛИЗ: ДИНАМИКА ДОСТУПНОСТИ СТАТИНОВ В УКРАИНЕ

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Ключевые слова: фармакоэкономика; статины; фармацевтический рынок; ассортимент лекарственных препаратов; динамика; показатель адекватности платежеспособности

Заболевания системы кровообращения – основная причина инвалидности и преждевременной смертности в Украине. Большим количеством РКИ и мета-анализов доказана высокая профилактическая эффективность применения статинов для снижения риска ССЗ. Цель исследования – анализ динамики стоимости и экономической доступ-

ности лекарственных препаратов статинов в Украине в период 2012-2015 гг. Динамику цен на отдельные препараты статинов определяли по данным системы «Фармакостандарт» компании «Морион». Для оценки экономической доступности статинотерапии использовали показатель адекватности платежеспособности. По результатам исследования установлено, что на фармацевтическом рынке Украины представлен достаточный ассортимент лекарственных препаратов статинов. За период с 2012 г. по 2015 г. отмечается положительная динамика структуры рынка – увеличение ЛП отечественного производства и их доли в структуре рынка. С 2014 г. отмечается рост цен для абсолютного большинства лекарственных препаратов группы статинов как отечественного, так и зарубежного производства – в среднем по группе на 42,1% и 101,4% соответственно. Динамика показателя адекватности платежеспособности свидетельствует об уменьшении экономической доступности препаратов статинов для украинского потребителя в период с 2012 г. по 2015 г. При этих условиях возможность первичной и вторичной статинопрофилактики ССЗ обеспечивается высокой экономической доступностью отечественных дженериков, ассортимент которых за последние четыре года вырос на 38%. Необходимы меры в системе охраны здоровья, способствующие повышению доступности и объемов потребления статинов в Украине.

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PRIORITY MODERN AND PROMISING AREAS OF THE PROFESSIONAL ACTIVITY OF A CLINICAL PHARMACIST AT DIFFERENT STAGES OF DEVELOPMENT OF CLINICAL PHARMACY IN UKRAINE

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Key words: clinical pharmacy; pharmaceutical care; professional activity of a clinical pharmacist

Clinical pharmacy now is at the stage of intensive development, its key points gradually being implemented in practical healthcare in Ukraine. The regulatory support of the activity of a clinical pharmacist, methodological aspects, as well as definition of his/her role and place in different areas of the national healthcare are important and necessary for the successful implementation of this process. A comparative study of the existing and promising directions of the clinical pharmacist's professional activity at different stages of the clinical pharmacy development has been conducted. According to the results of the study conducted three main modern blocks (15 directions) of the professional activity of a clinical pharmacist at the present stage of development of clinical pharmacy in Ukraine have been identified: I) information and terminology; II) methodological-didactic, III) expert and formulary. The block (4 directions) of the promising professional activity has been also determined, namely: creation of expert systems (mobile medical applications); analysis of cases on-line; participation in writing grant projects; search and development of new classification systems of clinical and pharmaceutical interventions. All directions of the clinical pharmacist activity can be combined in a new, in our opinion, two-vector concept – management of drug-related problems (DRPs) (identification, analysis, standardization, clinical and pharmaceutical intervention, pharmacoeconomic studies, etc.) and formation of the messages of pharmaceutical care (including assessment of its quality). However, we consider that according to the vectors of further development of clinical pharmacy the professional directions of the clinical pharmacist may vary.

In Ukraine, clinical pharmacy (CP) is at the stage of rapid development, its key provisions are gradually being introduced in practical healthcare (HC). The regulatory support of the activity of a clinical pharmacist (CPst), methodological aspects, as well as definition of his/her role and place HC areas are important and necessary for the successful implementation of this process. At the same time, the outlined range of problems makes it possible to continue research in this area with a shift in focus to other areas of the CPst activity and his/her promising place in the healthcare system of Ukraine, which is being reformed [2, 3, 4]. Over time, the CP vector has changed from medicines to a particular patient, it is focused on the needs of the patient in relation to drugs, ways of their administration, drug interactions, rationalization of pharmacotherapy (PT) by management of drug-related problems (DRPs) and pharmaceutical care (PC) [1, 6].

The aim of the work was to compare the existing directions and identify the promising areas of the professional activity of CPst taking into account stages of the CP development.

Materials and Methods

The study object was the professional activity of CPst. Such methods as system analysis, analytical and comparative, forecasting and modeling were used.

Results and Discussion

According to the results of our study 3 main blocks of the CPst professional activity at the present stage of the CP development in Ukraine have been identified: I) information and terminology; II) methodological-didactic; III) expert and formulary. Further for each of the given blocks we identified, in our opinion, the most urgent priority areas (n=15). Then we classified the following as the Ist block (n=5): 1) the evidence search and special evaluation of the clinical and pharmaceutical information; 2) formation of evidential essays as to the clinical requests obtained from doctors; 3) the CPst participation in the work of Drug Information Centres; 4) creation and distribution of clinical and pharmaceutical communications; 5) development of the terminology and conceptual apparatus (bibliosemantic study, interpretation of definitions, processing of glossaries) at all stages of the modern development of CP.

The methodological-didactic block provides for (n=4): 1) development of individual PC models aimed at the medical staff and patients; 2) application of DRP management technologies and determination of the level of drug adherence; 3) conducting workshops, trainings, 5-minute speeches for professionals involved in the drug process; 4) development of the CPst electronic portfolio (*e*-database; *e*-catalogues, *email*-newsletter).

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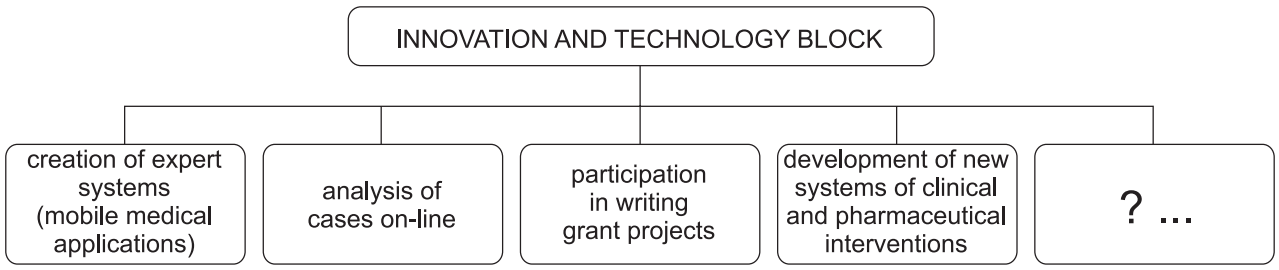

Fig. 1. The promising areas of the CPst professional activity

In particular, the "Information and Retrieval Evidence Base of CPst" database is being developed at the Department of Clinical Pharmacy, Pharmacotherapy and Medical Standardization.

We classified the following as the expert and formulary block (n=6): 1) technical support and revision of the National Formulary (participation in improvement of individual appendices and formulary articles for drugs); 2) management of the formulary drug lists; 3) participation in the system of pharmacovigilance (monitoring of adverse reactions of drugs in healthcare institutions, minimization of the risks of PT complications); 4) the expert assessment of PT by medical records; 5) the work of CPst as part of PT committees in healthcare institutions; 6) participation in clinical trials of drugs.

Taking into account the current challenges and the rapid development of innovation technologies the CPst should daily improve his/her knowledge and skills in accordance with vectors of further development of CP. In this regard, 4 priority, in our opinion, and promising areas of the CPst professional activity (Fig. 1) were predicted: creation of expert systems (mobile medical applications); analysis of *cases on-line*; participation in writing grant projects; search and development of new classification systems of clinical and pharmaceutical interventions integrated into the 4th block – innovation and technology.

It should be noted that the CPst professional activity is not limited to the aforementioned promising areas and can involve a range of many other directions, such as participation in the clinical audit, PT monitoring, pharmacogenetic testing, etc., depending on the specific character of the CP development and features of the healthcare system in Ukraine and in accordance with the passport of CPst specialty.

The CP modern development has led to computerization of many processes. However, in Ukraine this area of CP has not been almost worked out, it is necessary to develop and implement electronic expert systems (medical mobile apps), in particular in Ukrainian, and those that are adapted to the realities of the modern domestic clinical practice. In view of the above, development of such applications based on the popular operating systems for mobile devices (*Symbian, Windows Mobile, Android, iPhone, iOS*); medical services (*mHealth*-industry) designed to work with medical data (collection and analysis of medical records about the health status of the patient, in order to facilitate clinical decision-making) is considered to be a promising area of the CPst activity. Similar electronic systems of prescriptions and automated dose delivery systems, electronic monitoring of drug use, etc., have already been created abroad. Among the most famous free mobile apps that simplify and facilitate the daily professional activities of the CPst are: *EBM Calculator, Drug Interaction, Pharmacology, Drug Guide, Medical & Drug Dictionary, Medscape, Medication Guide, Normal Lab Values, MedCalc 3000 Complete, Cardio Drug Interaction*, etc.

There are also free mobile apps for patients to manage their own health, which allow monitoring certain indicators at home in case of chronic diseases (monitoring of the blood pressure, heart rate, or a device for measuring blood sugar levels, arrhythmia, etc.), as well as programs that help to increase adherence of patients to their own PT (reminder of the time to take a medicine, especially if they are more than one, indicating the dose, administration regimen concerning meals (before, after or during meals) and comments about the possible interactions and side effects, what to do in case of missing a dose, and if necessary, contact (mobile phone, e-mail) with the doctor, etc.)): *Glucose Calculator, CV Risk Calculator, BMI Calculator, SPAC Drug Adherence, Adherence Project, Dose cast – Medication Reminder, myHealth, Medicine Assistant, MediSafe Meds & Pill Reminder,* etc.

The intensive development of new educational technologies in medicine and pharmacy requires some changes in professionally-oriented approaches to the CPst activity. At the stage of the CP implementation into the practical health-care the CPst assessed the PT using only a retrospective analysis of drug administration records. However, this method made it impossible to carry out the actual intervention in the PT process, direct communication with the patient and prevention of DRP. Taking into account the abovementioned we consider it relevant

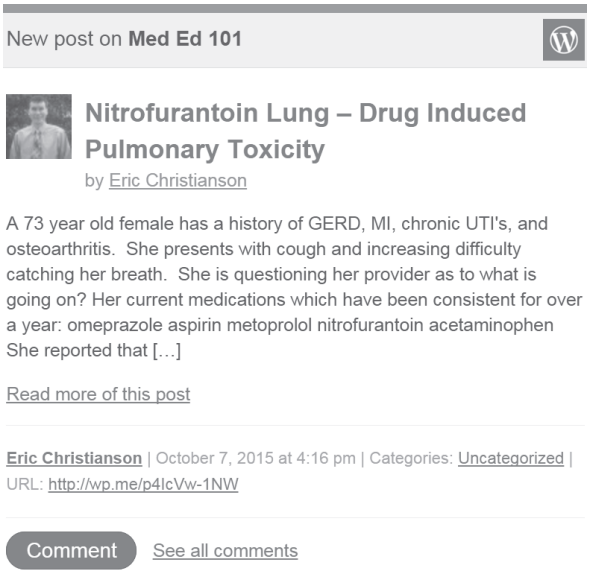

Fig. 2. An example of the case received to e-mail

to conduct prospective studies in order to assess the PT scheme of a specific patient during inpatient or outpatient treatment. In this perspective, in our opinion, the *on-line* analysis of *case*s by individual statements of doctors (Fig. 2) is one of the promising areas, which will provide the professional advice, prevent the DRP development and carry out pharmaceutical intervention at the stage of the PT. We believe that this approach will correspond to the modern patient-oriented concept of the CP.

At the same time, the cases analysed can be a great learning material for continuing professional development of the CPst at the undergraduate and postgraduate levels.

The next area of the CPst professional activity, in our opinion, may be involvement of this specialist in writing grant projects for integration of the international experience to the domestic CP. In particular, in 2014 the EU launched a programme of research and innovation – Horizon 2020, which will last until 2020. The project provides for scientific cooperation in order to search for new and promising areas of research through the support of *Future and Emerging Technologies* [5].

Today, the key CPst tool to evaluate PT is PCNE methodology to identify DRP. At the same time, the search for new less labour-intensive classification systems as to the CPst pharmaceutical interventions compared to different PCNE versions continues. In particular, the Swiss scientists have developed the *GSASA V2* classification system, which is easier to deal with and more promising in terms of documentation for pharmaceutical interventions in daily practice of the CPst, and contains 5 categories and 41 subcategories [7]. Improvement of the system of identifying DRP that are inherent to the national clinical practice at different stages of its development, in our opinion, is one of the priority and promising areas of the CPst professional activity in Ukraine. Separately, it should be noted that summarizing all the above, today all areas of the CPst activity can be narrowed down to a new two-vector concept – DRP management (identification, analysis, standardization, clinical and pharmaceutical intervention, pharmacoeconomic studies, etc.), DRP and formation of the corresponding PC messages (including assessment of its quality). All other areas are either arising out of the above or related to them.

CONCLUSIONS

1. According to the results of the study conducted three blocks (15 directions) of the modern professional activity and one block (4 directions) of the promising professional activity of a clinical pharmacist in Ukraine have been identified. At the same time, we consider that according to the vectors of further development of clinical pharmacy the professional directions of the clinical pharmacist may vary, but the focus on a patient will be basic and unchanged.

2. Thus, our long-term vision of clinical pharmacy is to build an interdisciplinary team of all professionals related to the process of pharmacotherapy with the support of an effective patient-oriented tailored strategy, modern innovative technologies and to provide consistently high standards of pharmaceutical care.

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ПРІОРИТЕТНІ СУЧАСНІ ТА ПЕРСПЕКТИВНІ НАПРЯМКИ ФАХОВОЇ ДІЯЛЬНОСТІ КЛІНІЧНОГО ПРОВІЗОРА НА РІЗНИХ ЕТАПАХ РОЗВИТКУ КЛІНІЧНОЇ ФАРМАЦІЇ В УКРАЇНІ

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Ключові слова: клінічна фармація; фармацевтична опіка; фахова діяльність клінічного провізора

В Україні клінічна фармація перебуває на етапі інтенсивного розвитку, її ключові положення поступово впроваджуються у практичну охорону здоров'я. Важливими та необхідними для успішної реалізації цього процесу є нормативне та правове забезпечення діяльності клінічного провізора, методологічні аспекти, а також визначення його ролі та місця у різних напрямках охорони здоров'я. Нами проведено порівняльне дослідження існуючих та перспективних напрямків фахової діяльності клінічного провізора з урахуванням етапів розвитку клінічної фармації. За результатами проведеного дослідження визначено 3 основні блоки (15 напрямків) фахової діяльності клінічного провізора на сучасному етапі розвитку клінічної фармації в Україні: I) інформаційно-термінологічний; II) методологічно-дидактичний; III) експертно-формулярний. Також ми виокремили 1 блок (4 напрямки) перспективної фахової діяльності клінічного провізора в Україні, а саме: створення експертних систем (мобільних медичних додатків); розбір «case»-випадків в on-line режимі; участь у написанні грантових проектів; пошук і розробка нових класифікаційних систем клініко-фармацевтичних втручань. Окремо зазначимо, узагальнюючи все вищенаведене, що сьогодні всі напрямки діяльності клінічного провізора можна звести до нової, на наш погляд, двовекторної концепції – менеджмент ліко-пов'язаних проблем (виявлення, аналіз, стандартизація, клініко-фармацевтичні втручання, фармакоекономічні дослідження тощо) та формування відповідних меседжів фармацевтичної опіки (включно з оцінкою її якості). Разом із тим ми вважаємо, що відповідно до векторів подальшого розвитку клінічної фармації професійні напрямки клінічного провізора можуть змінюватися.

ПРИОРИТЕТНЫЕ СОВРЕМЕННЫЕ И ПЕРСПЕКТИВНЫЕ НАПРАВЛЕНИЯ ПРОФЕССИОНАЛЬНОЙ ДЕЯТЕЛЬНОСТИ КЛИНИЧЕСКОГО ПРОВИЗОРА НА РАЗНЫХ ЭТАПАХ РАЗВИТИЯ КЛИНИЧЕСКОЙ ФАРМАЦИИ В УКРАИНЕ

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Ключевые слова: клиническая фармация; фармацевтическая опека; профессиональная деятельность клинического провизора

В Украине клиническая фармация находится на этапе интенсивного развития, ее ключевые положения постепенно внедряются в практическое здравоохранение. Важными и необходимыми для успешной реализации этого процесса является нормативное и правовое обеспечение деятельности клинического провизора, методологические аспекты, а также определения его роли и места в разных направлениях здравоохранения. Проведено сравнительное исследование существующих и перспективных направлений профессиональной деятельности клинического провизора с учетом этапов развития клинической фармации. По результатам проведенного исследования определены 3 основных блока (15 направлений) профессиональной деятельности клинического провизора на современном этапе развития клинической фармации в Украине: I) информационно-терминологический; II) методологично-дидактический, III) экспертно-формулярный. Также мы выделили 1 блок (4 направления) перспективной профессиональной деятельности клинического провизора в Украине, а именно: создание экспертных систем (мобильных медицинских приложений); разбор «case»-случаев в on-line режиме; участие в

написании грантовых проектов; поиск и разработка новых классификационных систем клинико-фармацевтических вмешательств. Отдельно отметим, обобщая все вышесказанное, что сегодня все направления деятельности клинического провизора можно свести к новой, на наш взгляд, двухвекторной концепции – менеджмент проблем, связанных с лекарствами (выявление, анализ, стандартизация, клинико-фармацевтические вмешательства, фармакоэкономические исследования и т. п.) и формирование соответствующих меседжей фармацевтической опеки (включая оценку ее качества). Вместе с тем мы считаем, что в соответствии с векторами дальнейшего развития клинической фармации профессиональные направления клинического провизора могут изменяться.

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THE QUALITY ANALYSIS OF PHARMACOTHERAPY OF PATIENTS WITH SCIATICA

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Key words: back pain; sciatica; pharmacotherapy; retrospective analysis of drug prescriptions; VEN analysis; frequency analysis

The article presents the results of the rationality assessment for pharmacotherapy of patients with sciatica on the basis of pooled VEN/ frequency analysis. A retrospective analysis of medication administration records of 112 patients diagnosed with sciatica has been conducted. A total of 61 TNs (46 INN) were prescribed to patients with sciatica. The total number of prescriptions was 964, the number of prescriptions per a patient – 8.6, indicating polypharmacy. The main directions of pharmacotherapy of patients with sciatica have been determined. They are anti-inflammatory and analgesic (non-opioid analgesics, NSAIDs, local anesthetics), antispasmodic (muscle relaxants), perfusion therapy to improve microcirculation and hemodynamics; they comply with the requirements of the current regulations – Clinical Protocol of medical care for patients with dorsalgia (2007). Comparison of the results of VEN and frequency analysis indicates that there are non-essential drugs with the metabolic action in the doctor's prescriptions, such as deproteinized blood derivative (actovegin), L-lysine aescinat, etc. In case of prescribing a significant number of non-essential drugs with the metabolic action leading to polypharmacy the use of antisecretory drugs, in particular proton pump inhibitors, to prevent complications in the gastrointestinal tract, which may be caused by NSAIDs, is insufficient. A possible way to increase the rationality of pharmacotherapy of patients with sciatica is to reduce the number of prescriptions of non-essential drugs that will reduce the number of prescriptions to a patient.

Back pain takes a leading place among painful musculoskeletal syndromes in terms of the number of disability days of the working population [1, 2, 8, 10]. Over the lifetime, about 70-80% of people experience at least one episode of back pain. In 15-20% of patients, acute back pain is transformed into chronic one. Back pain is one of the most common causes of disability among persons of different age, disability occurs in 10-20% of patients. Due to the fact that the peak incidence occurs in people of the working age, the problem of back pain has also the economic value. The economic damage of the state includes not only the direct costs of medical care, but also indirect costs – in the form of social benefits because of temporary or permanent disability, and damage caused by the backlog of work, as well as reduced efficiency [1, 2, 8, 10]. In the USA the annual direct costs associated with the treatment of back pain are estimated in 26.3 billion USD [11], and indirect costs caused by the lost working days due to the illness make up about 2% of the annual compensation for this reason [7].

Sciatica is a pathological condition characterized by appearance of pain along the sciatic nerve and in the lumbosacral region. This syndrome occurs in the case of pathological changes in the spine, hip joint, muscles and fasciae, as well as diseases of internal organs. Sciatica can lead to permanent performance degradation without timely and effective treatment [1, 2]. Medical and socio-economic importance of sciatica is caused by increase in disease incidence of people of the working age due to the spread of risk factors for the disease development, such as the lack of exercise, hard physical labour, poor posture, stress, pathological lordosis and kyphosis, increased body weight, pregnancy, etc. [1, 2, 6, 8, 9]. The above sciatica effects and development conditions necessitate its timely and effective treatment.

In case of the limited funds for healthcare the issue of the rational use of available resources and reduction of the cost for treatment of common diseases, such as sciatica, is urgent. One solution to this problem is an effective treatment of patients by means of the rational prescription of drugs selected on the basis of assessment of efficiency, safety and cost of the treatment. This goal is achieved by using the results of clinical and economic studies [5].

The aim of this study is to evaluate the rationality of prescriptions to patients with sciatica based on the results of VEN/ frequency analysis.

To achieve this goal, the following tasks were performed: a retrospective analysis of medication administration records of patients with sciatica was conducted; the main directions of pharmacotherapy were determined as a result of frequency analysis of drug prescriptions for patients with sciatica; compliance of pharmacotherapy with the current regulations was assessed based on the results of formal VEN analysis of drug prescriptions.

Materials and Methods

The assessment of the rationality level for pharmacotherapy of patients with sciatica was per-

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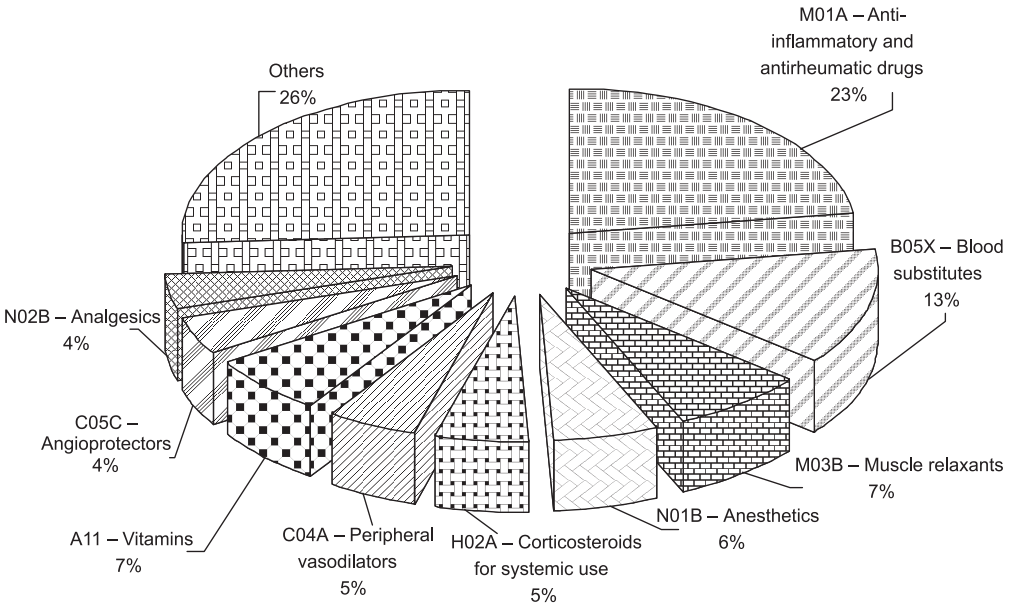

Fig. 1. Distribution of various pharmacotherapeutic groups of drugs by the frequency of prescriptions

formed using pooled VEN/frequency analysis. Frequency analysis is an assessment of the frequency of using a drug for the treatment of patients with a particular disease in a healthcare institution [5]. In this study, the frequency analysis of prescriptions was conducted according to the International Nonproprietary Names (INN), drug trade names (TNs), pharmacological groups, and the proportion of patients who received drugs of particular pharmacological groups. The formal VEN analysis involved the distribution of drugs by their significance into two categories: V – vital, and N – non-essential [5]. The drug was referred to category V by the presence of INN in the current Clinical Protocol (CP) of medical care for patients with sciatica [4] and in the National Drug Formulary (NDF, the Vth edition 2013) [3], and to category N – in case of its absence.

Results and Discussion

The analysis of regulations has indicated that pharmacotherapy of sciatica is determined by the current CP for patients with dorsalgia (Order of the Ministry of Health of Ukraine No. 275 dated 03.08.2007). According to this document the drug treatment of sciatica involves the use of the main groups of drugs. They are nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, muscle relaxants, anticonvulsants, anxiolytics, antidepressants, drugs with the chondroprotective action, drugs that improve microcirculation, regional and central hemodynamics, reduce venous congestion and tissue hydration; drugs with the metabolic action, as well as drug blockades (epidural sacral, selective radicular, etc.) with long-acting glucocorticoids (GCs) and a local anesthetic. Physio-, reflex and manual therapy, as well as exercise therapy are recommended for patients.

The rationality of drug prescriptions to patients with sciatica was assessed based on the results of frequency and VEN analysis. A retrospective analysis of medication administration records of 112 patients diagnosed with sciatica and treated at the Therapeutic Department of the district healthcare institution in the Poltava region in 2013 was conducted. A large proportion of patients were male patients – 64 patients, a smaller proportion – female – 50 patients, respectively. The average age of the patients was 56 ± 8.6 years old.

A total of 61 TNs (46 INN) were prescribed to patients with sciatica. The total number of prescriptions was 964, the number of prescriptions per a patient – 8.6, indicating polypharmacy. The average cost for the course of treatment per a patient was UAH 368.51. The average time for an inpatient in the hospital was 6 days.

Frequency analysis was conducted at the first stage of the study. It characterizes the frequency of prescriptions of a specific drug and its rating and proportion in the total number of prescriptions. Frequency analysis by pharmacological groups makes it possible to get an idea of the prevailing areas of pharmacotherapy. Comparison of the results of frequency analysis by pharmaceutical groups according to the current CP of treatment provides the opportunity to assess the degree of compliance of pharmacotherapy with the existing regulations of the Ministry of Health of Ukraine [5].

The results of frequency analysis summarized by pharmaceutical groups are shown in Fig. 1.

Drugs from 25 pharmacotherapeutic groups were used for the pharmacotherapy of patients with sciatica. It was found that anti-inflammatory and analgesic therapies were the prevailing areas of treating patients with sciatica. The following pharmacotherapeutic groups of drugs were used:

Table

Leading drugs (TOP-10) by the frequency of prescriptions among trade names

Drugs	Dosage form	Manufacturer	Frequency of prescriptions	Prescriptions, %	Patients, %
Saline solution	Solution for injection, 0.9%, 200 ml	Niko LLC (Ukraine, Makiivka)	60	6.22	53.57
Dexamethasone	Solution for injection, 4 mg, 1 ml amp., No. 10	DZ DNTSLZ LLC (Ukraine, Kharkiv)	52	5.39	46.43
Novocaine	Solution for injection, 20 mg/ml, 2 ml amp., No. 10	Darnytsia PJSC (Ukraine, Kyiv)	52	5.39	46.43
Tolperil	Solution for injection, 1 ml amp., No. 5	Zdorovya LLC (Ukraine, Kharkiv)	52	5.39	46.43
Euphyllin	Solution for injection, 20 ml, 5 ml amp., No. 10	Niko LLC (Ukraine, Makiivka)	48	4.98	42.86
Saline solution	Solution for injection, 0.9%, 100 ml vial	Niko LLC (Ukraine, Makiivka)	48	4.98	42.86
Vitamin B_{12}	Solution for injection, 0.05%, 1 ml amp., No. 10	Galychpharm PC (Ukraine, Lviv)	44	4.56	39.29
L-lysine aescinat	Solution for injection, 1 ml, 5 ml amp., No. 10	Galychpharm PC (Ukraine, Lviv)	40	4.15	35.71
Reumoxicam	Tabl., 7.5 mg, No. 20	Farmak LLC (Ukraine, Kyiv)	40	4.15	35.71
Analgin	Solution for injection, 500 mg/ml, 2 ml amp., No. 10	Lekhim-Kharkiv CJSC	36	3.73	32.14

M01A – Anti-inflammatory and antirheumatic drugs, they were 22.7% of the total cost of prescriptions, one patient was prescribed two drugs from this group; N01B – Anesthetics – 5.7% of the total number of prescriptions, they were received by 50% patients; H02A – Corticosteroids for systemic use – 5.3% of the total number of prescriptions, 46.4% of patients received them; A11D – Vitamins (mainly vitamins with the neurotrophic action: B_1, B_6, B_{12} and their complex preparations) – 6.6% of the total number of prescriptions, they were prescribed to 57.1% of patients. Therapy to relieve spasms of skeletal muscles and reduce pain included prescription of muscle relaxants (M03B) – 7.4% of the total number of prescriptions, 64.2% of patients received these drugs.

Reperfusion therapy used to improve microcirculation and hemodynamics was 13% prescriptions, some patients received simultaneously two drugs from this group.

Peripheral vasodilators (papaverine hydrochloride, dibazol) that were 5% of the total number of prescriptions were taken by 43% of patients, probably to improve hemodynamics of the nerve and muscle tissue [5].

Prescription of drugs from other pharmacotherapeutic groups was 25.7%, i.e. it was less. It is worth noting that antisecretory drugs, preferably omeprazole (24 prescriptions) and ranitidine (4 prescriptions), which were prescribed for prevention of gastrointestinal complications against the background of anti-inflammatory therapy with the use of NSAIDs and corticosteroids, were taken only by 25% of patients although two anti-inflammatory drugs were prescribed to almost everyone of them, parenterally and orally. Despite the significant risk of gastrointestinal complications when combining two NSAIDs [12, 13] prescription of antisecretory drugs is insufficient.

Thus, comparison of these main directions of pharmacotherapy with those defined by the current CP for patients with sciatica (Order of the Ministry of Health of Ukraine No. 275 dated 03.08.2007) shows that they are the same in general. These are such areas as anti-inflammatory and analgesic therapy included prescription of NSAIDs, analgesics, anesthetics, corticosteroids, muscle relaxants and preparations of neurotrophic vitamins (B_1, B_6, B_{12} and their complexes). All patients were treated with parenteral dosage forms, including NSAIDs, vitamins, and they also received perfusion therapy with metabolic drugs to improve microcirculation and hemodynamics.

Leading drugs (TOP-10) by the frequency of prescriptions (FP) among INN were saline solution (FP – 108), NSAID diclofenac sodium (FP – 84), muscle relaxant of the central action tolperisone hydrochloride (FP – 72), local anesthetic procaine (FP – 56), corticosteroid of the systemic action dexamethasone (FP – 52), NSAID ketorolac (FP – 48) and meloxicam (FP – 48), vasodilator theophylline (FP – 48), vitamin with the neurotrophic effect cyanocobalamin (FP – 44), metabolic drug L-lysine aescinat (FP – 40).

Leading drugs (TOP-10) among TNs are given in Table. Comparison of the results of frequency ana-

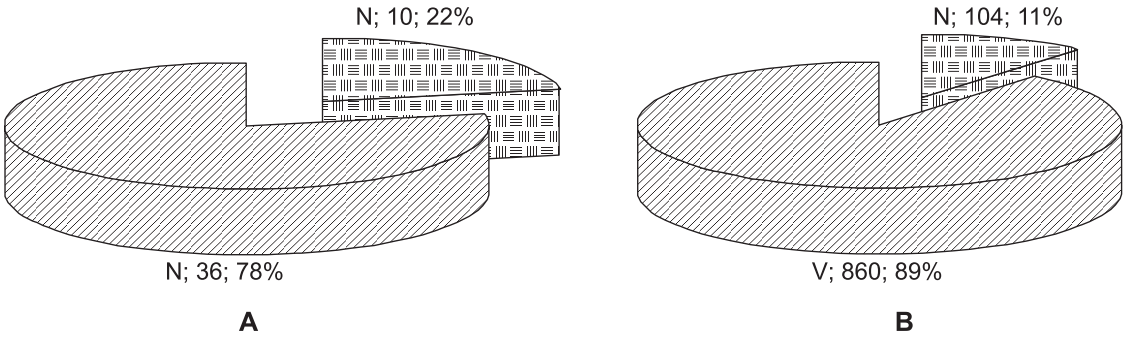

Fig. 2. A – distribution of the prescribed drugs by INN for categories V – vital and N – non-essential;
B – proportion of the drugs of categories V (vital) and N (non-essential) in the total number of prescriptions

lysis by INN and TNs has shown that the leaders by the frequency of prescriptions are drugs used to provide the main areas of pharmacotherapy of sciatica determined by the current CP. In general, the group of leading drugs included generic drugs that were more economically affordable for a Ukrainian patient.

At the next stage VEN analysis was conducted, and this allowed evaluating the compliance of pharmacotherapy of patients with a specific pathology with the current treatment protocols. The formal VEN analysis conducted has shown that out of 46 INN prescribed for the treatment of patients with sciatica 36 (78%) belong to category V – vital, 10 (22%) drugs – to category N – non-essential (Fig. 2A). The group of drugs of category N included drugs of the metabolic action: L-lysine aescinat, deproteinized hemoderivative (actovegin), citicoline, meldonium dihydrate, propionate dihydrate, enzyme preparation serratiopeptidase, etc.

Comparison of the results of frequency and VEN analysis (Fig. 2B) shows that drugs of category V (vital) make up 89% of all prescriptions, and drugs of category N (non-essential) – 11%. These are the drugs with the low level of evidence-based efficiency.

Therefore, vital drugs make up 89% of prescriptions of doctors for patients with sciatica. This demonstrates a sufficiently high degree of compliance of drug prescriptions with the current treatment protocol and NDF, the Vth ed., 2013, existing at the time of study, which is a standard of the pharmaceutical component of medical care.

CONCLUSIONS

1. In general, the main areas of the therapy of patients with sciatica comply with the requirements of the current clinical protocol. Leaders by the frequency of prescriptions are drugs used to provide the main directions of pharmacotherapy of sciatica.

2. The results of the formal VEN analysis show a certain level of compliance of pharmacotherapy with the current regulations – the most INN prescribed belong to the category of vital drugs: 78% of the number of INN prescribed, and 89% of the total number of prescriptions, respectively. A possible way to increase the rationality of pharmacotherapy of patients with sciatica is to reduce the number of prescriptions of non-essential drugs that will reduce the number of prescriptions to a patient.

3. In case of prescribing a significant number of non-essential drugs with the metabolic action leading to polypharmacy the use of antisecretory drugs to prevent complications in the gastrointestinal tract, which may be caused by NSAIDs, is insufficient.

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АНАЛІЗ ЯКОСТІ ФАРМАКОТЕРАПІЇ ХВОРИХ НА ЛЮМБОІШІАЛГІЮ

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Ключові слова: біль у спині; люмбоішіалгія; фармакотерапія; ретроспективний аналіз призначень лікарських засобів; VEN-аналіз; частотний аналіз

Наведені результати оцінки раціональності фармакотерапії хворих на люмбоішіалгію на основі сукупного VEN/частотного аналізу. Був проведений ретроспективний аналіз листків призначень 112 пацієнтів з діагнозом люмбоішіалгія. Усього хворим на люмбоішіалгію було призначено 61 ТН (46 МНН). Загальна кількість призначень склала 964, кількість призначень на одного хворого – 8,6, що свідчить про поліпрагмазію. Встановлені основні напрямки фармакотерапії хворих на люмбоішіалгію: протизапальна і аналгетична (неопіоїдні аналгетики, НПЗЗ, місцеві анестетики), антиспастична (міорелаксанти), перфузійна терапія для поліпшення мікроциркуляції і гемодинаміки, які відповідають вимогам чинних нормативних документів: клінічному протоколу медичної допомоги хворим на дорсалгії (2007 р.). Співставлення результатів VEN- і частотного аналізу свідчить, що в призначеннях лікарів присутні другорядні лікарські засоби метаболічної дії: актовегін, L-лізину есцинат та ін. На тлі призначення значної кількості другорядних препаратів, що призводило до поліпрагмазії, недостатнім є застосування антисекреторних засобів, зокрема інгібіторів протонної помпи, з метою профілактики ускладнень з боку шлунково-кишкового тракту, що можуть бути спричинені застосуванням НПЗЗ. Можливим шляхом підвищення раціональності фармакотерапії хворих на люмбоішіалгію є зменшення кількості призначень другорядних ЛЗ, що дозволить зменшити кількість призначень одному хворому.

АНАЛИЗ КАЧЕСТВА ФАРМАКОТЕРАПИИ БОЛЬНЫХ ЛЮМБОИШИАЛГИЕЙ

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Ключевые слова: боль в спине; люмбоишиалгия; фармакотерапия; ретроперспективный анализ назначений лекарственных средств; VEN-анализ; частотный анализ

Приведены результаты оценки рациональности фармакотерапии больных с люмбоишиалгией на основе совокупного VEN/частотного анализа. Был проведен ретроспективный анализ листков назначений 112 пациентов с диагнозом люмбоишиалгия. Всего больным было назначено 61 ТН (46 МНН). Общее количество назначений составило 964, количество назначений на одного больного – 8,6, что свидетельствует о полипрагмазии. Установлены основные направления фармакотерапии больных с люмбоишиалгией: противовоспалительная и анальгетическая (неопиоидные анальгетики, НПВС, местные анестетики), антиспастическая (миорелаксанты), перфузионная терапия для улучшения микроциркуляции и гемодинамики, которые соответствуют требованиям действующих нормативных документов: клинического протокола медицинской помощи больным с дорсалгиями (2007 г.). Сопоставление результатов VEN- и частотного анализа свидетельствует, что в назначениях врачей присутствуют второстепенные лекарственные средства метаболического действия: актовегин, L-лизина эсцинат и др. На фоне назначения значительного количества второстепенных препаратов, что приводило к полипрагмазии, недостаточным является применение антисекреторных средств, в частности ингибиторов протонной помпы, с целью профилактики осложнений со стороны желудочно-кишечного тракта, которые могут вызываться применением НПВС. Возможным путем повышения рациональности фармакотерапии больных с люмбоишиалгией является уменьшение количества назначений второстепенных ЛС, что позволит уменьшить количество назначений одному больному.

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ANALYSIS OF AFFORDABILITY OF THE FIRST LINE ANTIHYPERTENSIVE DRUGS FOR THE UKRAINIAN PATIENTS

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Key words: hypertension; coefficient of the solvency adequacy; affordability ratio; unified clinical protocol

Hpertension is one of the major medical and social problems in our country and around the world due to its significant prevalence and serious consequences, and this fact has determined the object and the aim of our study. The aim of the study was to determine affordability of the first line antihypertensive drugs recommended by the Unified Clinical Protocol of Medical Care to Patients with Hypertension (UCPMC) and presented at the pharmaceutical market of Ukraine in 2013-2014 for the Ukrainian patients. Two indicators were used to characterize the level of affordability of antihypertensive drugs: Ca.s and A. Ca.s determines the percentage of the average wage to be paid by the patient for the price of 1 package of a drug, and the greater value it has, the less affordable is the drug. The affordability ratio A shows the relationship between the growth of the living wage based on the index of growth of the drug price and the increase in the minimum wage. The study has revealed that the first line antihypertensive drugs (TNs) on the basis of 36 INNs and 35 fixed combinations were presented at the Ukrainian pharmaceutical market in 2013 and 2014. In 2014 the increase in the value of Ca.s for all INNs and all combinations was observed. It indicates the tendency towards decrease in affordability of drugs. However, by the absolute value most of Ca.s values are still in the range of highly affordable drugs, and it is provided by the presence of a great number of generic drugs at the market. The dynamics of A values has also confirmed the tendency towards decrease in affordability of antihypertensive drugs and their combinations. For example, 9 INNs and 5 combinations had A < 1 in 2013, and 32 INNs and 28 combinations – in 2014. This tendency of decrease in affordability of drugs necessitates introduction of socioeconomic measures to support the impoverished population of Ukraine; these measures may include reimbursement of expenditures on antihypertensive therapy at the expense of the state.

Cardiovascular disease ranks first among causes of death, disability and inability to work of the population. Hypertension (HTN) is the most common chronic disease that leads to development of a variety of vascular and cardiac complications [2].

In Ukraine, the prevalence of HTN among circulatory diseases is 46.8%, and almost half of the patients have cardiovascular diseases (CVD). Among the costs for the treatment of CVD the costs associated with the in-patient treatment of patients (60%) prevail [4].

Hypertension is one of the major medical and social problems in our country and around the world due to its significant prevalence and serious consequences. According to the WHO experts in the future mortality from hypertension will increase, firstly, due to aging of the population, and secondly, – to increasing prevalence of such risk factors as obesity, physical inactivity, diabetes, smoking, psycho-emotional stress, etc., in the population of many countries [3].

Hypertension is a disease of the cardiovascular system that develops due to the dysfunction of vasoregulative centers, followed by disturbances in the system of neurohumoral and renal mechanisms, and is characterized by increased blood pressure, secondary functional and organic changes in target organs [5].

The most relevant groups of drugs to treat hypertension include the following first-line drugs: angiotensin-converting-enzyme inhibitors (ACE inhibitors), calcium antagonists (CA), beta-blockers (β-blockers), angiotensin II receptor blockers (ARBs) and diuretics [7].

It is quite logical for each person to obtain the maximum therapeutic effect at minimum cost. But the high incidence rate, frequency of complications, disability and administration of drugs throughout later life indicate significant economic costs for patients. Taking all this into account it is relevant today to conduct the pharmacoeconomic evaluation of the treatment of hypertension and substantiate expediency for selecting a drug to optimize costs [8].

The aim of the study is to determine affordability of the first line antihypertensive drugs recommended by the Unified Clinical Protocol of Medical Care to Patients with Hypertension (UCPMC) in Ukraine in 2013-2014 for the Ukrainian patients.

Materials and Methods

Data on hypotensive drugs were taken from Morion research and retrieval system "Likarski zasoby" [4] for 2013-2014. Drugs for the analysis were selected on the basis of antihypertensive drugs included in the Unified Clinical Protocol of Medical Care to Patients with Hypertension for 2012 and recommended for the treatment of hypertension. They are presented in Table 1 [7].

To determine affordability of antihypertensive drugs, the coef-

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Table 1

Drugs for treating hypertension recommended by the unified clinical protocol

The I-st line antihypertensive drugs	
PhT group	INN
ACE inhibitors	Enalapril, Captopril, Quinapril, Lisinopril, Moexipril, Perindopril, Ramipril, Spirapril, Fosinopril
Angiotensin II receptor blockers	Candesartan, Losartan, Olmesartan, Irbesartan, Eprosartan, Telmisartan, Valsartan
Long-lasting calcium antagonists	Amlodipine, Lacidipine, Lercanidipine, Nifedipine, Felodipine, Diltiazem, Verapamil
β-Blockers	Atenolol, Betaxolol, Bisoprolol, Metoprolol, Nebivolol
Diuretics	Hydrochlorothiazide, Indapamide, Furosemide, Torasemide, Acetazolamide, Spironolactone and Eplerenone

ficient of the solvency adequacy (Ca.s) and the affordability ratio (A) [3] were calculated by the formula I and II, respectively:

$$Ca.s = P/W_{a.w.} \times 100\%, \quad (I)$$

where: P – is the weighted average price of 1 package of a drug for a certain period (a year);
$W_{a.w.}$ – is the average wage for a certain period (a year) [6].

Ca.s determines the percentage of the average wage to be paid by the patient for the price of 1 package of a drug. The lower the value of Ca.s is, the more affordable the antihypertensive drug is for the patient. Drugs with Ca.s of more than 15% are of low affordability, from 5% to 15% – of average affordability and less than 5% – highly affordable.

$$A = I_x \times Z_{min} / (I_s \times V_k), \quad (II)$$

where: Z_{min} – is the minimum wage in the country;
V_k – is the living wage;
I_x – is the index of the minimum wage change ($I_x = Z_n / Z_{n-1}$, Z_n – is the wage within the year under study, Z_{n-1} – is the minimum wage for the preceding year);
I_s – is the consolidated index of the drug price for the same period ($I_s = C_n / C_{n-1}$, C_n – is the average price within the year under study, C_{n-1} – is the average drug price for the preceding year).

The A ratio shows the relationship between the indexed minimum wage and the product between the living wage and the consolidated index of the drug price. The affordability ratio is equal to one and is more satisfactory to provide availability of the drug to the public (A ≥ 1); it means that the minimum wage increases in proportion to the increase in the drug price, or even faster.

Results and Discussion

According to the analysis conducted 36 INNs and 35 combinations of the first line antihypertensive drugs recommended by the Unified Protocol for treating HTN were presented at the Ukrainian pharmaceutical market in 2013 and 2014. Availability of drugs increased in 2014. According to the coefficients of the solvency adequacy calculated (Tab. 2) the cost of 1 package of drugs studied for the Ukrainian patient was from 0.19% (Furosemide) to 10.4% (Eplerenone) in 2013, and from 0.26% (Atenolol) to 12.9% (Eplerenone) of the average monthly wage – in 2014.

Eprosartan, Telmisartan, Eplerenone and 5 combination drugs were of average affordability for patients with HTN in 2013, and Olmesartan, Eprosartan, Eplerenone and 5 combination drugs (Fig.) – in 2014. The following antihypertensive drugs were the most affordable both in 2013 and in 2014 for the Ukrainian patients:

- Furosemide – Ca.s 0.19% (2013) and 0.51% (2014);
- Atenolol – Ca.s 0.21% (2013) and 0.26% (2014);
- Propranolol – Ca.s 0.35% (2013) and 0.47% (2014);
- Enalapril – Ca.s 0.52% (2013) and 0.49% (2014).

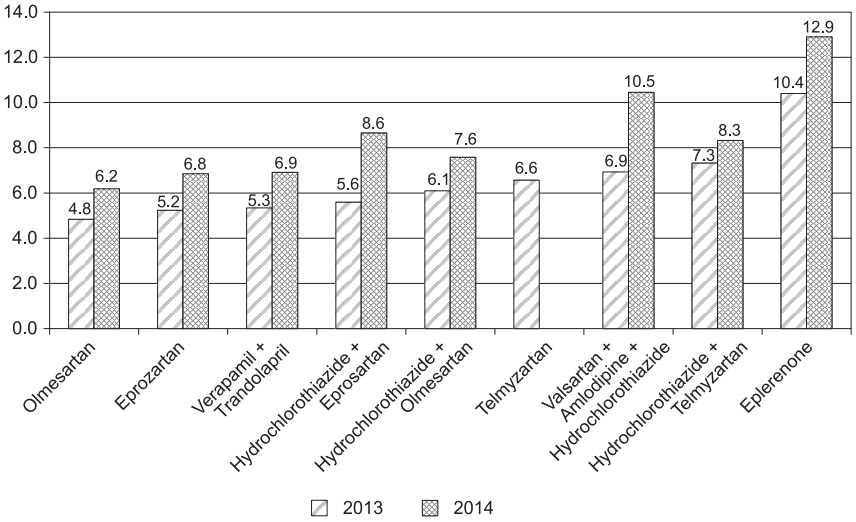

Fig. The least affordable antihypertensive drugs for patients in 2013-2014 by Ca.s

Table 2

Coefficients of the solvency adequacy and affordability ratios

No.	INN	Ca.s		A in 2012/2013	A in 2012/2013
		2013	2014		
1	2	3	4	5	6
1	Hydrochlorothiazide	0.6	0.76	0.98	0.81
2	Indapamide	1.16	1.63	1.03	0.73
3	Furosemide	0.19	0.51	0.95	0.37
4	Torasemide	4.3	4.67	1.04	0.95
5	Spironolactone	1.38	2.14	0.97	0.66
6	Eplerenone	10.4	12.9	0.99	0.83
7	Amiloride + Hydrochlorothiazide	1.5	1.8	1.09	0.86
8	Hydrochlorothiazide + Triamterene	1.64	2.15	0.83	0.79
9	Propranolol	0.35	0.47	0.94	0.76
10	Metoprolol	1.2	1.3	1.25	0.99
11	Atenolol	0.21	0.26	1.21	0.83
12	Betaxolol	2.28	2.74	1.07	0.86
13	Bisoprolol	1.0	1.26	1.23	0.82
14	Nebivolol	1.91	2.0	1.29	0.98
15	Carvedilol	1.61	2.12	1.02	0.78
16	Bisoprolol + Hydrochlorothiazide	1,50	2.01	0.88	0.77
17	Atenolol + Chlorthalidone	0.52	0.92	0.98	0.58
18	Felodipine + Metoprolol	3.61	4.03	0	0.92
19	Amlodipine + Atenolol	1.67	2.26	0.74	0.76
20	Atenolol + Nifedipine + Chlorthalidone	1.37	1.61	1.0	0.88
21	Bisoprolol + Amlodipine	2.46	3.53	1.15	0.72
22	Amlodipine	1.52	1.66	0.92	0.95
23	Felodipine	2.43	3.04	1.04	0.82
24	Nifedipine	1.23	1.18	1.86	1.08
25	Lacidipine	2.39	2.69	1.11	0.91
26	Lercanidipine	2.97	4.32	1.25	0.71
27	Verapamil	1.32	1.58	1.033	0.87
28	Diltiazem	1.03	1.84	1.04	0.58
29	Amlodipine + Hydrochlorothiazide	2.28	2.85	1.04	0.82
30	Captopril	0.39	0.67	1.01	0.61
31	Enalapril	0.52	0.49	1.16	1.1
32	Lisinopril	0.89	1.05	1.26	0.88
33	Perindopril	2.23	2.84	0.96	0.81
34	Ramipril	1.99	2.3	1.04	0.89
35	Fosinopril	1.52	1.91	1.13	0.82
36	Spirapril	3.35	3.31	1.12	1.04
37	Moexipril	2.26	3.13	0.84	0.74
38	Zofenopril	1.54	2.19	0	0.72
39	Hydrochlorothiazide + Captopril	0.45	0.57	1.0	0.81
40	Hydrochlorothiazide + Enalapril	0.8	0.87	11.75	0.95
41	Enalapril + Indapamide	1.16	1.18	1.04	1.01

Continuation of Table 2

1	2	3	4	5	6
42	Hydrochlorothiazide + Lisinopril	1.88	1.4	0.77	1.38
43	Indapamide + Perindopril	2.8	3.54	1.04	0.87
44	Hydrochlorothiazide + Ramipril	1.99	2.36	1.02	0.87
45	Hydrochlorothiazide + Quinapril	2.18	3.07	1.01	0.73
46	Hydrochlorothiazide + Fosinopril	1.92	2.6	1.09	0.76
47	Hydrochlorothiazide + Zofenopril	3.04	4.2	0	0.75
48	Enalapril + Lercanidipine	2.79	3.26	1.08	0.88
49	Amlodipine + Lisinopril	2.36	2.79	1.12	0.86
50	Perindopril + Amlodipine	2.61	3.28	1.37	0.82
51	Enalapril + Nitrendipine	3.03	3.38	1.07	0.92
52	Ramipril + Amlodipine	1.24	3.46	1.66	0.37
53	Amlodipine + Lisinopril	2.36	1.883	1.09	1.29
54	Verapamil + Trandolapril	5.34	6.9	1.0	0.8
55	Losartan	1.52	1.92	1.07	0.81
56	Eprosartan	5.23	6.84	1.08	0.79
57	Valsartan	2.84	3.8	1.09	0.77
58	Irbesartan	3.18	3.14	1.9	1.04
59	Candesartan	2.44	2.54	1.15	0.99
60	Telmisartan	6.56	4.49	1.07	1.5
61	Olmesartan	4.83	6.18	1.07	0.8
62	Hydrochlorothiazide + Losartan	2.28	3.0	1.09	0.78
63	Hydrochlorothiazide + Eprosartan	5.59	8.64	0	0.66
64	Valsartan + Hydrochlorothiazide	3.04	3.68	1.15	0.85
65	Hydrochlorothiazide + Irbesartan	4.51	4.38	1.11	1.06
66	Hydrochlorothiazide + Candesartan	3.42	3.68	1.11	0.96
67	Hydrochlorothiazide + Telmisartan	7.31	8.32	1.05	0.91
68	Hydrochlorothiazide + Olmesartan	6.09	7.57	1.03	0.83
69	Valsartan + Amlodipine	3.76	4.61	0.98	0.84
70	Losartan + Amlodipine	1.91	1.85	1.08	1.06
71	Valsartan + Amlodipine + Hydrochlorothiazide	6.92	10.45	0	0.68

According to the results of the calculation of affordability ratios (A) (Table 2) of the drugs studied 9 INNs and 5 combinations of drugs had the affordability ratio less than one in 2013, and 32 INNs and 28 combinations of drugs – in 2014. It indicates the sharp decrease in affordability of antihypertensive drugs for the Ukrainian patients in 2014. Combinations of Hydrochlorothiazide with Lisinopril and Amlodipine with Lisinopril, as well as Telmisartan became more affordable in 2014 as compared to 2013.

CONCLUSIONS

The analysis has shown that practically there are no changes in the range of drugs to treat hypertension recommended by the Unified Clinical Protocol of Hypertension Treatment of 2012 at the pharmaceutical market of Ukraine in 2014 as compared to 2013. According to the coefficients of the solvency adequacy calculated the most affordable for Ukrainian patients in 2013 – 2014 were the drugs of the following INNs: Furosemide, Atenolol, Propranolol and Enalapril. According to affordability ratios 8 INNs and 6 combinations of drugs had D<1 in 2013, and 15 INNs and 16 combinations of drugs – in 2014. It indicates the sharp decrease in affordability of antihypertensive drugs for the Ukrainian patients in 2014.

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АНАЛІЗ ДОСТУПНОСТІ АНТИГІПЕРТЕНЗИВНИХ ПРЕПАРАТІВ ПЕРШОЇ ЛІНІЇ ДЛЯ УКРАЇНСЬКИХ ПАЦІЄНТІВ

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Ключові слова: гіпертонічна хвороба; показник адекватності платоспроможності; коефіцієнт доступності; уніфікований клінічний протокол

Гіпертонічна хвороба є однією з найважливіших медичних і соціальних проблем як у нашій країні, так і в усьому світі в силу своєї значної поширеності і тяжких наслідків, що і визначило об'єкт і мету даного дослідження. Метою дослідження було визначення доступності для українських пацієнтів антигіпертензивних препаратів першої лінії, рекомендованих «Уніфікованим клінічним протоколом медичної допомоги хворим з артеріальною гіпертензією» (УКПМД) і представлених на фармацевтичному ринку України у 2013-2014 роках. Для характеристики ступеня доступності антигіпертензивних лікарських засобів використовували два показники: Ca.s. та D. Показник Ca.s визначає % середньої заробітної плати українця, необхідний для покупки однієї упаковки препарату, чим більше значення він має, тим менш доступний препарат. Коефіцієнт доступності D показує співвідношення між зростанням прожиткового мінімуму з урахуванням індексу росту ціни на препарат та зростання мінімальної заробітної плати. Проведені дослідження дозволили встановити, що протягом 2013-2014 років на фармацевтичному ринку України були представлені антигіпертензивні ЛП (ТН) першої лінії на основі 36 МНН та 35 фіксованих комбінацій. У 2014 році за усіма МНН та для усіх комбінацій спостерігаємо збільшення показника Ca.s, що свідчить про тенденцію до зниження доступності ЛП. Але за абсолютною величиною більшість значень Ca.s ще знаходиться у проміжку високодоступних лікарських препаратів, що забезпечується наявністю великої кількості генеричних препаратів на ринку. Динаміка значень D також підтвердила тенденцію до зниження доступності антигіпертензивних ЛП та їх комбінацій. Так, у 2013 році D < 1 мали 9 МНН і 5 комбінацій, а у 2014 році – 32 МНН та 28 комбінацій. Встановлена тенденція до зниження доступності ЛП обумовлює необхідність введення соціально-економічних заходів для підтримки збіднілого населення України, серед яких може бути реімбурсація витрат на гіпотензивну терапію за рахунок держави.

АНАЛИЗ ДОСТУПНОСТИ АНТИГИПЕРТЕНЗИВНЫХ ПРЕПАРАТОВ ПЕРВОЙ ЛИНИИ ДЛЯ УКРАИНСКИХ ПАЦИЕНТОВ

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Гипертоническая болезнь является одной из важнейших медицинских и социальных проблем как в нашей стране, так и во всем мире в силу своей значительной распространенности и тяжелых последствий, что определило объект и цель данного исследования. Целью исследования было определение доступности для украинских пациентов антигипертензивных препаратов первой линии, рекомендованных «Унифицированным клиническим протоколом медицинской помощи больным с артериальной гипертензией» (УКПМП) и представленных на фармацевтическом рынке Украины в 2013-2014 годах. Для характеристики степени доступности антигипертензивных лекарственных средств использовали два показателя: Ca.s. и D. Показатель Ca.s определяет % средней

заработной платы украинцев, необходимый для покупки одной упаковки препарата, чем большее значение он имеет, тем менее доступен препарат. Коэффициент доступности D показывает соотношение между ростом прожиточного минимума с учетом индекса роста цены на препарат и ростом минимальной заработной платы. Проведенные исследования позволили установить, что в течение 2013-2014 годов на фармацевтическом рынке Украины были представлены антигипертензивные ЛП (ТН) первой линии на основе 36 МНН и 35 фиксированных комбинаций. В 2014 году по всем МНН и для всех комбинаций наблюдаем увеличение показателя Ca.s, что свидетельствует о тенденции к снижению доступности ЛП. Но по абсолютной величине большинство значений Ca.s еще находится в промежутке высокодоступных лекарственных препаратов, что обеспечивается наличием большого количества генерических препаратов на рынке. Динамика значений D также подтвердила тенденцию к снижению доступности антигипертензивных ЛП и их комбинаций. Так, в 2013 году D < 1 имели 9 МНН и 5 комбинаций, а в 2014 году – 32 МНН и 28 комбинаций. Установленная тенденция к снижению доступности ЛП обусловливает необходимость введения социально-экономических мероприятий для поддержания обедневшего населения Украины, среди которых может быть реимбурсация затрат на гипотензивную терапию за счет государства.

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COST EVALUATION OF THE ANTIHELICOBACTER THERAPY OF GASTRODUODENAL ULCERS

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Key words: peptic ulcer; duodenal ulcer; antihelicobacter therapy; cost of treatment

The results of cost evaluation of the antihelicobacter therapy regimen of gastroduodenal ulcers recommended by the Ukrainian unified clinical protocol of medical care to adult patients with this disease (order of the Ministry of Health of Ukraine No. 613 dated 03.09.2014), which is based on the principles of evidence-based medicine, are presented. It has been found that most medicines used in the antihelicobacter therapy regimen were presented at the pharmaceutical market of Ukraine in 2014 in sufficient quantities with a wide range of prices per a drug unit. The cost ranges of the antihelicobacter therapy are: the first-line therapy – from 87.50 to 3400.88 UAH (the triple therapy – from 181.44 to 3400.88 UAH; the sequential therapy – from 87.50 to 1837.65 UAH); the second-line therapy (quadrotherapy) – from 202.60 to 2059.19 UAH; the therapy of salvation – from 157.08 to 3298.93 UAH. The total costs of therapy for the patient with therapy of salvation are from 628.62 to 10596.65 UAH. The variants of the antihelicobacter therapy regimen have been proposed. They are formed from the medicines presented at the Ukrainian pharmaceutical market and the State Formulary of Ukraine, and have the lowest costs for the course of the antihelicobacter therapy of the disease. Their use is economically feasible for the Ukrainian low solvent patients with peptic and duodenal ulcers.

Peptic ulcer (PU) and duodenal ulcer (DU) are one of the expensive of gastroenterological diseases. The average annual cost of treating a patient with PU is from $ 959.60 to 2553.10 in South Korea, and $ 23819 in the USA [13]. The total cost of inpatient treatment (direct and indirect costs) of a patient with DU associated with *Helicobacter pylori* (*H. pylori*) is on average $ 708.60 in Russia [3]. In the USA more than $ 750 million are spent per year for the treatment of PU complicated with bleeding [8].

According to the international and national guidelines for treatment of gastroenterological patients the main treatment strategy of PU and DU associated with *H. pylori* is to conduct the antihelicobacter therapy (AHT) [7, 9-14]. The successful eradication of *H. pylori* contributes to activation of the regeneration process and scarring ulcers, reduces the probability of developing recurrence and complications. The basic requirements for AHT are good tolerability (the frequency of side effects is less than 5%), the effectiveness for the course of treatment is no longer than 7-14 days, the level of *H. pylori* eradication is not less than 80% and economic feasibility [9]. Antisecretory medicines (proton pump inhibitors (PPIs)), antibacterial medicines exhibiting the activity against *H. pylori* (most often amoxicillin, clarithromycin, tetracycline, metronidazole), and bismuth medicines having the cytoprotective and antibacterial properties are used for AHT [5, 9, 10, 12]. The cost of AHT constitutes a significant proportion of the costs for treating PU and DU. Each year more than 500 million EUR are spent only for the purchase of antisecretory medicines in Germany [4].

The aim of this work was to evaluate costs for AHT of PU and DU in adult patients in Ukraine.

The tasks of the study were as follows:

1) analysis of the assortment of medicines used for AHT of PU and DU at the pharmaceutical market of Ukraine;

2) determination of the cost range for the regimens of the first and second line of AHT, therapy of salvation per one adult patient in Ukraine;

3) formation of the least expensive AHT regimens from medicines presented at the pharmaceutical market of Ukraine.

Materials and Methods

The objects of our research were regimens of AHT recommended for treating PU and DU by unified clinical protocols of the primary, secondary (specialized) medical care "Peptic ulcer of the stomach and duodenum in adults" (order of the Ministry of Health of Ukraine No. 613 dated 03.09.2014) [7] created in accordance with the principles of evidence-based medicine:

I. The first-line therapy:

1) The triple therapy: PPI in a standard dose twice a day + amoxicillin, 1000 mg, twice a day + clarithromycin, 500 mg, twice a day for 10-14 days.

2) The triple therapy with allergy to penicillin: PPI in a standard dose twice a day + clarithromycin, 500 mg, twice a day + metronidazole, 500 mg, twice a day for 7-14 days.

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Table

The assortment of medicines used in the antihelicobacter therapy regimens of peptic and duodenal ulcers at the pharmaceutical market of Ukraine

International non-proprietary name	The number of TN in various dosage forms	The ratio of foreign / domestic TN	Price per a drug unit, UAH	The number of TN in the SFU
Proton pump inhibitors				
Omeprazole	26	16 / 10	5.45 – 178.79	11
Lansoprazole	8	5 / 3	32.99 – 92.53	6
Pantoprazole	30	25 / 5	25.61 – 269.04	19
Rabeprazole	15	11 / 4	17.09 – 953.64	10
Ezomeprazole	12	12/ 0	63.88– 1284.83	11
Antibacterial medicines				
Amoxicillin	22	14 / 8	17.25 – 153.11	16
Clarithromycin	39	29 / 10	37.93 – 426.88	28
Levofloxacin	50	27 / 23	59.89 - 1160.24	24
Metronidazole	21	9 / 12	5.90 – 66.94	10
Tetracycline	4	2 / 2	4.05 – 8.66	2
Tinidazole	2	2 / 0	15.08 – 52.42	2
Bismuth medicines				
Bismuth subcitrate	6	2 / 4	33.54 – 239.75	6

3) The sequential therapy: PPI in a standard dose twice a day + amoxicillin, 1000 mg, twice a day for 5 days with subsequent transition to PPI + clarithromycin, 500 mg, twice a day + metronidazole (or tinidazole), 500 mg, twice a day for 5 days.

II. The second-line therapy (quadrotherapy): PPI in a standard dose twice a day + bismuth subcitrate, 120 mg, 4 times a day + metronidazole, 500 mg, 3 times a day + tetracycline, 500 mg, 4 times a day for 10-14 days. It is prescribed when the triple therapy or sequential therapy is noneffective, or there is intolerance or resistance to clarithromycin.

III. The therapy of salvation: PPI in a standard dose twice a day + amoxicillin, 1000 mg, twice a day + levofloxacin, 500 mg, once a day or rifabutin, 300 mg, once a day for 10-14 days. It is prescribed when eradication of *H. pylori* is absent after the second course of treatment.

The standard daily doses of PPIs for the treatment of Helicobacter dependent diseases are: omeprazole – 40 mg, pantoprazole – 80 mg, rabeprazole – 40 mg, lansoprazole – 60 mg, ezomeprazole – 40 mg [1].

The assortment of trade names (TN) of medicines under study in Ukraine and the average retail price per a drug unit in the pharmacy network in 2014 were determined according to the market research system of medicines "Pharmstandard" of "Morion" company (November 2014) [6]. The presence of TN for medicines was assessed in the current State Formulary of Ukraine (SFU) (the 6-th ed.) [2]. This document regulates the rational choice of drug TN for pharmacotherapy of diseases. Costs for the use of medicines in the composition of AHT regimens for PU and DU per one patient were calculated per the course of treatment – 14 days (for sequential therapy – 10 days). Only costs on medicines were taken into account when calculating the cost.

Results and Discussion

The analysis of the assortment of PPIs, bismuth and antibacterial medicines in tablets used in the AHT regimens at the domestic pharmaceutical market has shown that most medicines of proton pump inhibitors, amoxicillin, clarithromycin and metronidazole medicines are presented in Ukraine by many TN (Table). These drugs are used in the AHT regimens most often. They are offered by several manufacturers. Therefore, their price range is sufficiently wide. It may significantly influence on the cost of treating a patient with PU and DU. Moreover, the antibacterial medicine levofloxacin prescribed only in the "therapy of salvation» is presented in Ukraine by the largest number of TN among the medicines studied. Rifabutin is its alternative in accordance with the clinical protocol [7]. Trade names of this medicine is absent at the Ukrainian pharmaceutical market. Most of the medicines studied are presented in various dosage forms (with different doses and the different number of tablets in a pack). This makes possible to reduce the cost of treatment by choosing the dosage form with minimal costs. It should be noted that not all TN of medicines for

AHT were present in the SFU (the 6-th ed.) (Table).

For all medicines included in the AHT regimens and presented at the Ukrainian pharmaceutical market the cost of the treatment course per an adult patient with PU and DU was calculated. Medicines of PPIs (omeprazole, pantoprazole, rabeprazole, lansoprazole, ezomeprazole), antibacterial medicines (amoxicillin, clarithromycin, tetracycline, metronidazole, tinidazole, levofloxacin) and bismuth subcitrate with minimum and maximum costs per a course of treatment were determined by the results of the calculations. The variants of the regimens under study were formed according to these calculations, and the cost range of the AHT regimen of PU and DU of the first and second-line therapy, therapy of salvation for one patient was identified.

The costs ranges of the antihelicobacter therapy are: the first-line therapy – from 87.50 to 3400.88 UAH (the triple therapy – from 181.44 to 3400.88 UAH; the sequential therapy – from 87.50 to 1837.65 UAH); the second-line therapy (quadrotherapy) – from 202.60 to 2059.19 UAH; the therapy of salvation – from 157.08 to 3298.93 UAH. The total costs for the patient in the therapy of salvation are from 628.62 to 10596.65 UAH.

The difficult socio-economic situation in Ukraine determines the choice of medicines by a doctor for regimens of AHT to patients with a low solvency. According to the results of calculations the variants of regimens studied were formed from the least costly medicines, and their cost per a course of treatment was calculated. Only TN of medicines from the SFU (the 6-th ed.) were included in these regimens:

I. The first-line therapy:

1) The triple therapy (14 days): Omeprazole "Pharmac" caps., 0.02 g, No.30 (14.84 UAH) + Kleron-MaxPharma "MaxPharma Limited" tabl., 250 mg, No.14 (151.76 UAH) + Gramox-A "Sperco Ukraine" caps., 500 mg, No.20 (48.72 UAH). The cost of the regimen is 215.32 UAH.

2) The triple therapy with allergy to penicillin (14 days): Omeprazole "Pharmac" caps., 0.02 g, No.30 (14.84 UAH) + Kleron-MaxPharma "MaxPharma Limited" tabl., 250 mg, No.14 (151.76 UAH) + Metrogil® "J.B. Chemicals & Pharmaceuticals" tabl., 200 mg, No.100 (14.84 UAH). The cost of the regimen is 181.44 UAH.

3) The sequential therapy (10 days): Omeprazole "Pharmac" caps., 0.02 g, No.30 (10.60 UAH) + Gramox-A "Sperco Ukraine" caps., 500 mg, No.20 (17.40 UAH) + Kleron-MaxPharma "MaxPharma Limited" tabl., 250 mg, No.14 (54.20 UAH) + Metrogil® "J.B. Chemicals & Pharmaceuticals" tabl., 200 mg, No.100 (5.30 UAH). The cost of the regimen is 87.50 UAH.

II. The second-line therapy (quadrotherapy) (14 days): Omeprazole "Pharmac" caps., 0.02 g, No.30 (14.84 UAH) + Vis-nol® "Pharmac" caps., 120 mg, No.100 (52.50 UAH) + Tetracycline hydrochloride "BCPP" tabl., 100 mg, No.20 (113.26 UAH) + Metrogil® "J.B. Chemicals & Pharmaceuticals" tabl., 200 mg, No.100 (21.98 UAH). The cost of the regimen is 202.58 UAH.

III. The therapy of salvation (14 days): Omeprazole "Pharmac" caps., 0.02 g, No.30 (14.84 UAH) + Gramox-A "Sperco Ukraine" caps., 500 mg, No.20 (48.72 UAH) + Leflocin® "Yuriya Farm" tabl., 500 mg, No.10 (93.52 UAH). The cost of the regimen is 157.08 UAH.

CONCLUSIONS

1. Most medicines used in the AHT regimens are presented at the pharmaceutical market of Ukraine in sufficient quantities with a wide range of prices per a drug unit. This gives opportunities for their rational choice for the treatment of patients with PU and DU taking into account the individual characteristics of the patient and his/her solvency.

2. The cost of the AHT regimens of PU and DU per one adult patient can be quite high in Ukraine and depends on representatives of PPIs, antibacterial medicines and bismuth medicines that are included in them. The lowest cost of the AHT regimens of PU and DU of the first and second-line therapy, the therapy of salvation has been determined using the following TN of these medicines (present in the current SFU (the 6-th ed.)): among PPIs medicines – Omeprazole "Pharmac" caps., 0.02 g, No.30; among clarithromycin medicines – Kleron-MaxPharma "MaxPharma Limited" tabl., 250 mg, No.14; among amoxicillin medicines – Gramox-A "Sperco Ukraine" caps., 500 mg, No.20; among metronidazole medicines – Metrogil® "J.B. Chemicals & Pharmaceuticals" tabl., 200 mg, No.100; among tetracycline medicines – Tetracycline hydrochloride "BCPP" tabl., 100 mg, No.20; among levofloxacin medicines – Leflocin® "Yuriya Farm" tabl., 500 mg, No.10; among bismuth medicines – Vis-nol® "Pharmac" caps., 120 mg, No.100. Using the regimens formed from these TN of medicines is economically feasible the Ukrainian low solvent patients with PU and DU.

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ОЦІНКА ВИТРАТ НА АНТИХЕЛІКОБАКТЕРНУ ТЕРАПІЮ ВИРАЗКОВОЇ ХВОРОБИ ШЛУНКА ТА ДВАНАДЦЯТИПАЛОЇ КИШКИ

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Ключові слова: виразкова хвороба шлунка; виразкова хвороба дванадцятипалої кишки; антихелікобактерна терапія; витрати на лікування

Представлені результати оцінки витрат на схеми антихелікобактерної терапії виразкової хвороби шлунка та дванадцятипалої кишки, рекомендовані українським уніфікованим клінічним протоколом надання медичної допомоги дорослим пацієнтам з даним захворюванням (Наказ МОЗ України №613 від 03.09.2014 р.), який створено з урахуванням принципів доказової медицини. Встановлено, що більшість лікарських препаратів, які використовуються у складі схем антихелікобактерної терапії, була наявна на фармацевтичному ринку України у 2014 році в достатній кількості з широким діапазоном цін за упаковку. Діапазон вартості антихелікобактерної терапії складає: перша лінія терапії – від 87,50 до 3400,88 грн (трикомпонентна терапія – від 181,44 до 3400,88 грн; послідовна терапія – від 87,50 до 1837,65 грн); друга лінія терапії (квадротерапія) – від 202,60 до 2059,19 грн; терапія «порятунку» – від 157,08 до 3298,93 грн. Загальна вартість терапії хворого, якому допомогла тільки терапія «порятунку», складає від 628,62 до 10596,65 грн. Запропоновані варіанти схем антихелікобактерної терапії, сформовані з лікарських препаратів, представлених на українському фармацевтичному ринку, наявні в Державному формулярі лікарських засобів України і мають найменшу вартість на курс антихелікобактерної терапії захворювання. Їх використання є економічно доцільним для українських пацієнтів з виразковою хворобою шлунка та дванадцятипалої кишки з низькою платоспроможністю.

ОЦЕНКА ЗАТРАТ НА АНТИХЕЛИКОБАКТЕРНУЮ ТЕРАПИЮ ЯЗВЕННОЙ БОЛЕЗНИ ЖЕЛУДКА И ДВЕНАДЦАТИПЕРСТНОЙ КИШКИ

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Ключевые слова: язвенная болезнь желудка; язвенная болезнь двенадцатиперстной кишки; антихеликобактерная терапия; затраты на лечение

Представлены результаты оценки затрат на схемы антихеликобактерной терапии язвенной болезни желудка и двенадцатиперстной кишки, рекомендованные украинским унифицированным клиническим протоколом предоставления медицинской помощи взрослым пациентам с данным заболеванием (Приказ МОЗ Украины

№613 от 03.09.2014 г.), который создан с учетом принципов доказательной медицины. Установлено, что большинство лекарственных препаратов, которые используются в составе схем антихеликобактерной терапии, присутствовали на фармацевтическом рынке Украины в 2014 году в достаточном количестве с широким диапазоном цен за упаковку. Диапазон стоимости антихеликобактерной терапии составляет: первая линия терапии – от 87,50 до 3400,88 грн (трикомпонентная терапия – от 181,44 до 3400,88 грн; последовательная терапия – от 87,50 до 1837,65 грн); вторая линия терапии (квадротерапия) – от 202,60 до 2059,19 грн; терапия «спасения» – от 157,08 до 3298,93 грн. Общая стоимость терапии больного, которому помогла только терапия «спасения», составляет от 628,62 до 10596,65 грн. Предложены варианты схем антихеликобактерной терапии, сформированные из лекарственных препаратов, которые представлены на украинском фармацевтическом рынке, присутствуют в Государственном формуляре лекарственных средств Украины и имеют наименьшую стоимость на курс антихеликобактерной терапии заболевания. Их применение экономически целесообразно для украинских пациентов с язвенной болезнью желудка и двенадцатиперстной кишки с низкой платежеспособностью.

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THE STUDY OF THE EFFECT OF COMORBIDITIES ON PHARMACOTHERAPY OF PATIENTS WITH LIVER CIRRHOSIS

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Key words: cirrhosis; comorbidity; frequency analysis; VEN analysis; drugs used to treat liver diseases

Recently, the incidence of liver cirrhosis has been increasing and the mortality is still high. The death rate from liver cirrhosis is 2% of all deaths of the world's population, and mortality is on the 5th place. The subject of the study was 190 medical records of patients diagnosed with liver cirrhosis in the Department of Gastroenterology of Ivano-Frankivsk Regional Clinical Hospital for 2012-2013. According to the analysis of gender, age, social characteristics, the area of residence and comorbidities in 190 patients with LC their generalized portrait has been represented. This is a man aged 51-60, who mostly comes from rural areas (57.4%), does not work in 66% of cases and has such comorbidities as chronic pancreatitis (66.3%), chronic gastroduodenitis (54.2%), chronic cholecystitis (48.9%). The results of frequency and formal VEN analyses of medication administration records of the patients indicate that they received substantial treatment of comorbidities (55% of the drugs prescribed). To optimize the treatment of patients with LC it is necessary, first of all, to develop a new protocol of medical care to patients with LC taking into account the data of evidence-based medicine, pharmacoeconomics and coordination with regulatory lists of drugs. It has been shown that the simultaneous treatment of LC and comorbidities leads to polypharmacy.

Recently, the incidence of liver cirrhosis (LC) has been increasing and the mortality is still high [2, 10]. Thus, in 2010 the death rate from LC was more than 1 million of people, it was 2% of all deaths of the world's population, and mortality was on the 5th place among the causes of death of people after coronary heart disease, cerebrovascular diseases, lung cancer, HIV infection/AIDS. Differences in mortality rates between countries are due to different levels of consumption of alcohol and the prevalence of viral hepatitis C and B. The European average age of death from LC is 59 years compared to 82-84 years for heart, lung diseases or stroke. Over the past 10 years, 5-fold increase in cases of LC in patients aged 35-55 was observed [10, 13]. In Ukraine, the number of patients with LC increased by 9.5% from 2006 to 2013, and mortality – by 19% [7].

The therapeutic measures in patients with LC are determined by their etiology, degree of activity and compensation, the presence of complications and comorbidities [1, 2, 4-6, 8, 9-11].

The aim of this study was to rank comorbidities of patients with LC and determine the extent of their influence on prescriptions of doctors by conducting the retrospective methods of clinical and economic analysis of pharmacotherapy.

Materials and Methods

The object of the study was the work of a particular healthcare institution (HCI) concerning organization of pharmaceutical provision of patients with LC. The subject of the study was 190 medical records of patients diagnosed with liver cirrhosis in the Department of Gastroenterology of Ivano-Frankivsk Regional Clinical Hospital for 2012–2013. Among the medical records 44.2% belonged to patients with mixed LC, 38.4% – with cryptogenic, 12.1% – viral, 3.2% – portal and 2.1% – biliary LC. A retrospective evaluation of the drugs prescribed was conducted using methods of frequency and formal VEN analysis. Frequency analysis of the therapy made it possible to assess its tendencies since it illustrates the opinions of doctors and the financial possibilities of patients. VEN analysis is distribution of drugs according to the importance of their prescription for the treatment of a particular disease (L.V.Iakovlieva, 2009). This analysis was conducted on formal grounds. Class V included drugs of the basic pharmacotherapy recommended by Protocol 1.14 "Care to Patients with Liver Cirrhosis" according to the Order of the Ministry of Health of Ukraine No. 271 dated 13.06.2005 "On Approval of Protocols of Medical Care in the Specialty of Gastroenterology" (hereinafter referred to as the "Protocol"); class E – drugs of adjunctive therapy according to the Protocol; class N – all other drugs prescribed. In addition, group V was analyzed according to belonging of its drugs to the main regulatory lists of drugs in Ukraine, namely: the National List of Basic Drugs and Medical Devices (Resolution of the CMU No. 333 dated 25.03.2009), the Budget List of Drugs (Resolution of the CMU No. 1071 dated 05.09.1996 amended), the National Drug Formulary (NDF) of the 4th ed. (Order

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Table 1

The age and gender distribution of patients with cirrhosis

Age	The number of patients, including	Men	Women
21-30	8 (4.2%)	5 (62.5%)	3 (37.5%)
31-40	34 (17.9%)	20 (58.8%)	14 (41.2%)
41-50	49 (25.8%)	34 (69.4%)	15 (30.6%)
51-60	70 (**36.9%**)	52 (74.3%)	18 (25.7%)
61-70	20 (10.5%)	13 (65%)	7 (35%)
71 and more	9 (4.7%)	5 (55.5%)	4 (44.5%)
Total	100%	-	

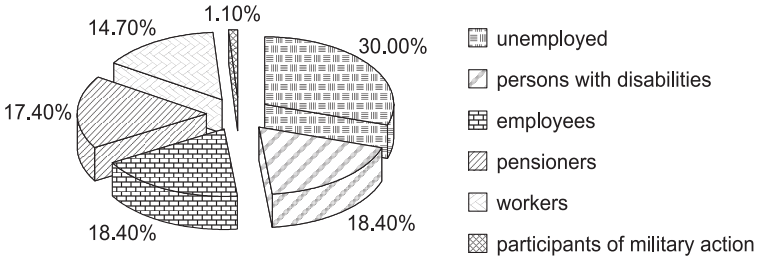

Fig. 1. Distribution of patients with LC by their social status

of the Ministry of Health of Ukraine No. 209 dated 28.02.2012) and the 5th ed. (Order of the Ministry of Health of Ukraine No. 251 dated 29.03.2013) corresponding to the years of treatment of patients, as well as the 6th ed. (Order of the Ministry of Health of Ukraine No. 252 dated 08.04.2014) and the 7th ed. (Order of the Ministry of Health of Ukraine No. 183 dated 30.03.2015) – for assessment.

Results and Discussion

The analysis of the inpatient medical records showed that there were 129 (67.9%) men and 61 (32.1%) women among 190 persons. The data obtained correlate with the literature data that state that men suffer LC 2 times more often than women [11, 12]. Table 1 shows a detailed gender analysis of patients in age groups with increment of 10 years.

Thus, both men and women aged 51-60 were ill more often. It confirms the tendency towards rejuvenation of persons with LC. The data of other researchers show that the average age of women with LC was 62.4 ± 8.5 in 2002, and 59.8 ± 8.2 in 2007 [11].

In our sample of medical records spontaneously formed the persons from rural areas dominated (57.4%), and urban citizens were 42.6%.

The results of the social status analysis of patients with LC are presented in Fig. 1. It showed that the percentage of unemployed among all patients was about 66%.

In addition to the basic diagnosis, patients had concomitant diagnoses, primarily a few of them.

Table 2

TOP-5 comorbidities in patients with liver cirrhosis

No.	Name of disease	Absolute number of patients	Relative number of patients, %
1	Chronic pancreatitis	126	66.3
2	Chronic gastroduodenitis	103	54.2
3	Chronic cholecystitis	93	48.9
4	Biliary dyskinesia	26	13.7
5	Diabetes mellitus type II	22	11.6

Table 2 shows the TOP-5 of comorbidities found in patients with LC.

According to the results of analysis in Table 2 it can be concluded that most comorbidities were related to the hepatobiliary system and belonged to pathologies of the pancreas, liver and biliary tract. There were also few complications of the basic diagnosis in patients with LC.

The next stage of work was to conduct retrospective clinical and economic analyses. As a result of frequency analysis of medication administration records, it was determined that there were 1,968 prescriptions of 197 trade names of drugs to 190 patients with LC (on average 10-11 drugs per a patient). The analysis revealed that the drugs belonged to 12 groups of the ATC classification and 6 items of dietary supplements (DS) (Fig. 2).

The data presented graphically in Fig. 2 show that leaders in ATC groups were the following groups: A – "Drugs that affect the digestive system and metabolism" (46.20%), C – "Drugs for the treatment of cardiovascular diseases" (15.23%), N – "Drugs to treat diseases of the nervous system" (10.66%). The wide range of drugs according to ATC suggests that patients received substantial treatment of comorbidities along with the LC therapy. Therefore, both the existence of basic disease complications and the presence of comorbidities significantly increase the number of drug prescriptions.

Table 3 shows the TOP-10 drugs by the frequency of prescriptions. Analysis of Table 3 shows that the top ten drugs include: 4 hepatoprotectors, 2 diuretic drugs and 1 drug from the groups of lactulose drugs, antiarrhythmic, vitamin K and proton pump inhibitors. When comparing the drugs prescribed most often in accordance with the requirements of the Protocol it was found that all of them were recommended for medical care to patients with LC.

Overall frequency analysis revealed that 32 hepatoprotectors

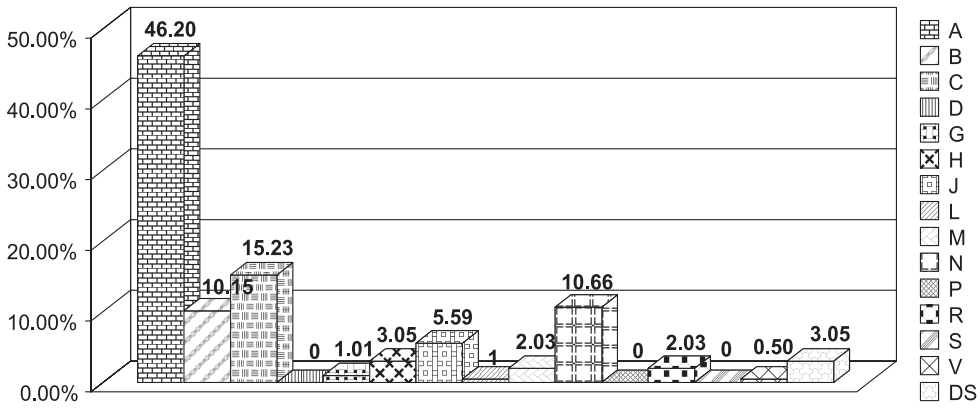

Fig. 2. Consumption of drugs by ATC classification groups

were prescribed to patients; it comprised 565 prescriptions (28.7%). This is the main group of drugs, along with the causal antiviral therapy, according to the Protocol which divides the drugs on the drugs of basic and adjunctive therapy. The first group, except for hepatoprotectors (including ursodeoxycholic acid and amino acids), includes enzyme, diuretic, antibacterial, β-blockers, probiotics and infusion drugs. The second one is hormonal preparations for hemostatic therapy, blood products, parenteral proton pump inhibitors and H_2 antagonists.

The formal VEN analysis of the consumed drugs was conducted to assess the rationality of prescriptions according to the recommendations of the Protocol (Fig. 3).

Hence, the compliance of the consumed drug therapy with the clinical protocol of medical care to patients with LC can be estimated in 45% (the amount of percent of drugs of classes V and E). But the Protocol was adopted in 2005. It has not been revised yet. It does not meet modern requirements of medical standardization: it has only general pharmacological groups of drugs, but not INN, and does not contain the recommended doses, presentation and conditions for drug administration.

Therefore, we analyzed the class V drugs for their presence in the social and economic regulatory lists of drugs in Ukraine. The analysis revealed that from 67 drugs of class V only 15 drugs (diuretics, antibiotics and infusion therapy drugs) were simultaneously included into all basic regulatory lists: the National List of Basic Drugs, Budget List of Drugs and NDF. They were for 22.39% of the basic therapy drugs. Drugs from the group of hepatoprotectors were not included into the National List of Basic Drugs. Instead, the Budget List contained 59 from 67 the basic drugs prescribed, they were 88.06%. And 55 basic therapy drugs

Table 3

TOP-10 drugs prescribed to patients with liver cirrhosis most often

No.	Name of drug	Absolute number of prescriptions	Relative number, %
1.	Verospiron caps., 100 mg, No. 30 (Gedeon Richter JSC, Hungary)	122	6.20
2.	Thiogamma Turbo sol. for inf., 1.2%, No. 1 (Woerwag Pharma GmbH & Co. KG, Germany)	87	4.42
3	Duphalac syrup, 667 g / 1000 ml, 500 ml (Solvay Pharmaceuticals/ Abbott Biologicals BV, The Netherlands)	78	3.96
4	Heptral lyoph. pwd. for sol. for inj., 400 mg, No. 5 (Hospira SP / Famar Lyehl, Italy / France / Greece)	68	3.45
5	Glutargin conc. for sol. for inf., 40%, 5 ml, No. 10 ("Zdorovye" Pharmaceutical Company, Ukraine)	68	3.45
6	Asparcam tab., No. 50 (Galychpharm JSC, Urkaine)	56	2.85
7	Essentiale sol. for inj., 250 mg / 5 ml, No. 5 (Ed. Nattermannend Sayi HmbH, Germany)	53	2.69
8	Furosemide sol for inj., 10 mg / ml, 2 ml, No. 10 ("Darnitsa" Pharmaceutical company, Ukraine)	51	2.59
9	Vicasol sol. for inj., 1%, 1 ml, No. 10 ("Darnitsa" Pharmaceutical company, Ukraine)	34	1.72
10	Controloc tab., resist. gastr., 40 mg, No. 28 (AltanaPharma AG, Germany)	31	1.57

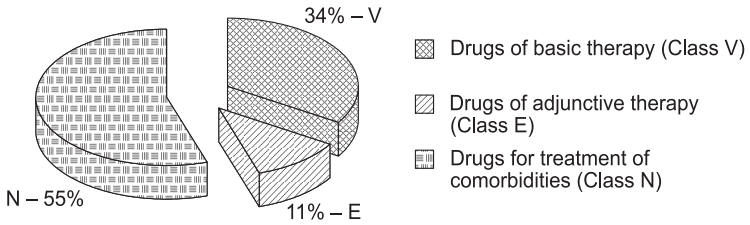

Fig. 3. The results of the formal VEN analysis for the therapy consumed by the patients with LC

were included in the NDF of the 4th (2012) and 5th (2013) editions. However, the NDF of the 6th edition (2014) limited a number of groups of hepatoprotectors (48 basic therapy drugs – 71.64%), and only ursodeoxycholic acid drugs, silymarin and amino acids remained in the NDF of the 7th edition (2015) (44 basic therapy drugs – 65.67%).

At the same time in the TOP-10 drugs (see Table 3) Thiogamma Turbo (Woerwag Pharma GmbH & Co. KG, Germany), Glutargin (Zdorovye, Ukraine) and Essentiale (Ed. Nattermannend Sayi HmbH, Germany), which were no longer formulary drugs according to the NDF of the 7th edition since April 2015, took the 2nd, 5th and 7th rating positions, respectively. Among the 4 most common hepatoprotectors, only Heptral (Hospira SP / FamarLyehl, Greece) was included in the last updated NDF. This fact shows the need to increase the motivation of physicians to a permanent treatment to use in their work the recommendations of the updated editions of the NDF of Ukraine.

Therefore, to optimize the treatment of patients with LC it is necessary, first of all, even not to revise it, but develop a new protocol of medical care to patients with LC taking into account the data of evidence-based medicine, pharmacoeconomics and coordination with regulatory lists of drugs, which also should be based on generally accepted approaches, namely evidence and economic feasibility.

At the same time treatment of patients with LC according to the US and UK Clinical Guidelines [3, 5] is not overloaded with drugs, and focuses on the lifestyle of the patient and pharmaceutical care. Here we see the main role of pharmacists in overcoming the problem of chronic liver diseases in general, and LC in particular. As the simultaneous treatment of patients with LC and comorbidities is the negative practice, it leads to polypharmacy being unacceptable in LC.

CONCLUSIONS

According to the analysis of gender, age, social characteristics, the area of residence and comorbidities in 190 patients with LC their generalized portrait can be represented. This is a man aged 51-60, who mostly comes from rural areas (57.4%), does not work in 66% of cases and has such comorbidities as chronic pancreatitis (66.3%), chronic gastroduodenitis (54.2%), chronic cholecystitis (48.9%).

The results of frequency and formal VEN analyses of medication administration records of the patients indicate that they received substantial treatment of comorbidities (55% of the drugs prescribed). Therefore, we consider it appropriate to recommend adherence to the formulary approach to inpatient treatment: first treat the underlying disease determining it by the risk value, and then proceed to the treatment of comorbidity. There is also a need to develop a new clinical protocol of medical care to patients with liver cirrhosis in Ukraine.

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ВИВЧЕННЯ ВПЛИВУ СУПУТНІХ ЗАХВОРЮВАНЬ НА ФАРМАКОТЕРАПІЮ ХВОРИХ НА ЦИРОЗИ ПЕЧІНКИ

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Ключові слова: цирози печінки; супутнє захворювання; частотний аналіз; VEN-аналіз; лікарські засоби для лікування захворювань печінки

У світі зростає захворюваність на цирози печінки (ЦП), а летальність залишається високою: рівень смертності від ЦП складає 2% від усіх смертей населення планети, а летальність є п'ятою причиною смерті людей. Предметом дослідження були 190 медичних карт хворих гастроентерологічного відділення Івано-Франківської обласної клінічної лікарні за 2012-2013 рр. із діагнозом ЦП. За результатом аналізу гендерних, вікових, соціальних ознак, місцевості проживання, наявності супутніх хвороб у пацієнтів досліджуваної спонтанної вибірки представлено їх узагальнений портрет. Це переважно чоловік 51-60 років, який здебільшого походить із сільської місцевості (57,4%), у 66% випадків не працює та має супутні захворювання: хронічний панкреатит (66,3%), хронічний гастродуоденіт (54,2%), хронічний холецистит (48,9%). Результати частотного та формального VEN-аналізів листків призначень пацієнтів свідчать, що вони отримали значне лікування супутніх хвороб (55% призначених препаратів). Для оптимізації лікування цієї категорії пацієнтів насамперед необхідно поновити Протокол медичної допомоги хворих на ЦП (наказ МОЗ України №271 від 13.06.2005 р.) із врахуванням даних доказової медицини, фармакоекономіки та узгодженням із регулюючими переліками лікарських засобів в Україні. Показано, що одночасне лікування хворих на ЦП та супутні захворювання призводить до поліпрагмазії.

ИЗУЧЕНИЕ ВЛИЯНИЯ СОПУТСТВУЮЩИХ ЗАБОЛЕВАНИЙ НА ФАРМАКОТЕРАПИЮ БОЛЬНЫХ НА ЦИРРОЗЫ ПЕЧЕНИ

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Ключевые слова: циррозы печени; сопутствующее заболевание; частотный анализ; VEN-анализ; лекарственные средства для лечения заболеваний печени

В мире растет заболеваемость на циррозы печени (ЦП), и остается высокой их летальность: уровень смертности от ЦП составляет 2% всех смертей населения планеты, а летальность является пятой причиной смерти людей. Предмет исследования – 190 медицинских карт больных гастроэнтерологического отделения Ивано-Франковской областной клинической больницы за 2012-2013 гг. с диагнозом ЦП. По результатам анализа гендерных, возрастных, социальных признаков, местности проживания, наличия сопутствующих болезней у пациентов исследуемой спонтанной выборки представлен их обобщенный портрет. Это преимущественно мужчина 51-60 лет, который в основном происходит из сельской местности (57,4%), в 66% случаев он не работает и имеет сопутствующие заболевания: хронический панкреатит (66,3%), хронический гастродуоденит (54,2%), хронический холецистит (48,9%). Результаты частотного и формального VEN-анализов листов назначений пациентов указывают, что 55% выписанных им препаратов были для лечения сопутствующих болезней. Для оптимизации фармакотерапии этой категории пациентов, в первую очередь, необходимо обновить Протокол медицинской помощи больных ЦП (приказ МЗ Украины №271 от 13.06.2005) с учетом данных доказательной медицины, фармакоэкономики и согласования с регулирующими перечнями лекарственных средств в Украине. Показано, что одновременное лечение ЦП и сопутствующих болезней ведет к полипрагмазии.

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THE ASSESSMENT OF COMPLIANCE OF THE INPATIENT STAGE PHARMACOTHERAPY WHEN TREATING RHEUMATOID ARTHRITIS WITH PROVISIONS OF INDUSTRY STANDARDS

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Key words: rheumatoid arthritis; inpatient treatment stage; frequency analysis; gastroprotective drug prevention

The ongoing monitoring of the inpatient stage of treatment is the necessary condition for improving the quality of pharmacotherapy of such costly diseases as rheumatoid arthritis (RA) and optimizing the costs for its implementation. According to the data of 100 case histories of patients with RA the use of glucocorticoids (GCs), non-steroidal anti-inflammatory drugs (NSAIDs) and gastroprotective drug prevention of complications associated with their use at the inpatient stage of treatment has been analyzed, and compliance of prescriptions with the provisions of the updated national unified clinical protocol of 2014 (UCPMC RA), as well as the recommendations of the European League Against Rheumatism (EULAR) in taking GCs and NSAIDs for rheumatoid diseases has been identified. It was formulated that GCs for systemic use and NSAIDs were prescribed according to the regimens specified in UCPMC RA and in compliance with the algorithm of the rational choice of NSAIDs for RA. It was determined that for the levels of prescriptions of GCs and NSAIDs set the gastroprotective drug prevention of complications associated with their use in the rheumatology department was carried out properly and according to the recommendations of UCPMC RA and EULAR. A high level of compliance by practitioners of a healthcare institution with the provisions of the current UCPMC RA has been determined, and it will allow both preventing in advance possible undesired effects of using GCs and NSAIDs and reducing the costs of their correction.

The ongoing monitoring of drug therapy at the inpatient stage of treatment and its compliance with the provisions of the industry standards of healthcare are significant steps to improve the quality of medical care and optimize the costs for its implementation. This analysis is especially important for ICD diseases with costly treatment and those diseases that affect people of the working age. Rheumatoid arthritis (RA) is one of these diseases, its peak incidence occurs in women aged 41 and men aged 45, i.e. the working age. According to epidemiological data approximately 20-30% of patients lose efficiency during the first 2-3 years of the disease, and up to 85% –within the following 8-11 years [4, 5]. According to estimates of most countries it is indirect costs (in particular those that are due to premature mortality, deterioration of the life quality, payments on sick leaves and disability) that represent a significant share in the expenditure pattern of RA [7, 8].

The updated national unified clinical protocol of medical care of 2014 (UCPMC RA) defines two areas of drug therapy for RA: 1) modification of the disease process aimed at slowing or stopping the radiographic progression, which is closely correlated with the expression of functional disorders; 2) reduction of symptoms with priority of pain relief in RA patients [5]. Glucocorticoids (GCs), non-steroidal anti-inflammatory drugs (NSAIDs) and analgesics are prescribed to reduce quickly exacerbation and suppression of the pain syndrome intensity in joints.

When using GCs the necessity for mandatory risk assessment of side effects development associated with their administration, and determination of the presence of comorbidities in the patient are specified in the evidence-based recommendations of the European League Against Rheumatism (EULAR). Attention is paid to the presence of the parallel treatment of NSAIDs, hypertension, gastric ulcer and duodenal ulcer, diabetes, chronic infections, bone fractures, etc. It is recommended to prescribe gastroprotective drugs (proton pump inhibitors (PPIs) or Misoprostol) to patients who are treated with GCs and concomitant NSAIDs, or as an alternative patients can be transferred to a selective inhibitor of cyclooxygenase-2 (the I-st level of evidence, with 95% CI: 91 (84-98), which is not characterized by gastrotoxicity [6].

The algorithm of the rational choice of a particular NSAID and the concomitant therapy (PPIs, acetylsalicylic acid) is shown in detail in UCPMC RA (2014). It is noted that selection of both classical NSAIDs, and COX-2 specific inhibitors without/or with PPIs depends on the presence and the number of risk factors in the GIT (previous events in the upper sections of the GIT, the age ≥ 65 years old, chronic administration of NSAIDs, concomitant use of GCs or aspirin) and in the CVS. In UCPMC RA there are also cases when prescription of any NSAIDs should be avoided [5].

The aim of our study was to analyze the use of GCs, NSAIDs and

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gastroprotective drug prevention of complications associated with the use of GCs, NSAIDs in patients with RA at the inpatient stage of treatment and to determine whether prescriptions are complied with the recommendations of EULAR and UCPMC RA of 2014.

Materials and Methods

The objects of the study were case histories of patients with RA who were treated in the rheumatology department of one of the regional clinical hospital. The following methods of research were used: a retrospective analysis of case histories and drug administration records of patients with RA; a supplementary method of clinical and economic analysis – frequency analysis, which at the inpatient treatment stage determines the proportion of patients who this or that pharmacotherapeutic group and/or drug (drugs) were prescribed to [6]; analytical (analysis of the EULAR recommendations for treating RA and the RA National Clinical Guidelines of 2014 (UCPMC RA)).

Results and Discussion

100 Case histories of patients with RA were analyzed, and 21 patients were diagnosed with the first stage of the disease (the process activity DAS_{28} <3.2), 67 and 12 patients – with the second stage (DAS_{28} 3.2-5.1) and the third stage (DAS_{28}>5.1), respectively. Concomitant diseases of the endocrine, cardiovascular, musculoskeletal and nervous systems were observed in the study range of case histories. The largest group (35.9% of all comorbidities) consisted of pathologies of the musculoskeletal system, namely spondylarthrosis, primary and secondary osteoarthritis, generalized osteoporosis, etc. The second place among all the comorbidities in RA patients is taken by diseases of the endocrine system, among which the most patients (34.6%) have a diagnosis of "glucocorticoid dependence."

Table

Frequency of prescriptions (%) of drugs of groups A02, H02 and M01 to patients with rheumatoid arthritis according to the data of the drug administration records taking into account the stages of the disease

ATC group	Frequency of prescriptions (in %)		
	Stages of RA		
	I stage	II stage	III stage
A02 – drugs for the treatment of acid-related diseases	71.42 %	91.04%	91.66%
H02 – GCs for systemic use	123.81%	137.31%	183.34%
M01 – anti-inflammatory antirheumatic drugs	100%	88.06%	100%

The frequency analysis conducted by these drug administration records made it possible to determine the proportion of patients who GCs, NSAIDs and PPIs were prescribed to.

According to the data of the frequency analysis at the inpatient stage of treatment GCs were prescribed to the patients with RA diagnosed with the I, II and III stage of the disease in 123.81%, 137.31% and 183.34% cases, respectively (Table). That is for the part of the patients various GC treatment regimens were used simultaneously or one after another: pulse therapy, combination background therapy (methotrexate + GCs orally) and local therapy. For rapid inhibition of the inflammatory activity and induction of remission in 28% of the RA patients with the stage I, in 59.7% and 100% of the patients with the stage II and III, respectively, the GC pulse therapy was used. It is believed that in contrast to the regular hormone therapy the GC pulse therapy causes no persistent side effects, no hormonal dependence and does not inhibit the adrenocortical function [1]. In practice, various regimens of the pulse therapy are used, and among them the methylprednisolone therapy (1.000 mg intravenously) has proven its efficacy in many studies [8]. Simultaneously with the aim of stabilizing the remission the second line of therapy – methotrexate + GCs (orally) – was prescribed. GCs were also used for topical application (intra-articular) as the additional method of eliminating RA complications.

The NSAIDs therapy was received by 100% of patients with the stage I of RA. Only parenteral forms of NSAIDs were prescribed to these patients; among them 57.14% were non-selective (n-NSAIDs), namely – diclofenac, and 42.86% – moderately selective in relation to COX-2 (ms-NSAIDs) – meloxicam. NSAIDs were prescribed to the majority (71.42%) of patients with the stage I of RA in combination with PPIs (pantoprazole and omeprazole). Taking into account the algorithm of the rational choice of NSAIDs presented in UCPMC RA, IPPs were not probably prescribed to other patients in the absence of risk factors in GIT and CVS, or vice versa – when combining of the high CVS and GIT risks. The presence of the own class-specific side effects in PPIs (the increased risk of intestinal infections, pneumonia, progression of osteoporosis, etc.) is also considered to be a contraindication for their use [2].

The proportion of patients with RA of II and III stage who received NSAIDs was 88.06% and 100%, respectively. Among parenteral forms of NSAIDs, ms-NSAIDs and n-NSAIDs were used in 75% and

85.7% cases, respectively. Among oral dosage forms ms-NSAIDs (Nimesulide) and selective NSAIDs (Celecoxib) were used in 100% of cases.

In the above levels of prescriptions of NSAIDs and GCs in patients with stages II and III of RA the drug gastroprotective therapy with PPIs (pantoprazole, omeprazole, esomeprazole) was used in 91.04% and 91.66% cases, respectively.

All NSAIDs prescribed in the healthcare institution, except for Nimesulide, are specified in the recommendations of UCPMC RA concerning the balanced use of NSAIDs for rheumatic diseases. It should be noted that Nimesulide is presented in National Drug Formularies of the 5th and 7th editions (2013-2015) with the recommendations for the symptomatic treatment of the pain syndrome in case of RA, osteoarthritis and other diseases of the musculoskeletal system. It is considered that tolerability of Nimesulide is better compared to n-NSAIDs. However, as to development of GIT bleeding and perforations, Nimesulide has no advantages over traditional NSAIDs [2].

Thus, the data of the structure of NSAIDs prescriptions analyzed indicate a balanced approach of medical practitioners to their choice and compliance with the provisions of UCPMC RA (2014) for the rational choice of NSAIDs for rheumatic diseases, as well as the recommendations of the National Drug Formulary.

Taking into account the amount of the PPIs administration this group of drugs was probably prescribed in the presence of clear indications to their use. One should be also considered the class-specific undesired side effects of these drugs (progression of osteoporosis, increased risk of intestinal infections, etc.), as well as the fact that 24% of patients were diagnosed with glucocorticoid-induced osteoporosis together with RA, and 54% – with hormonal dependence.

CONCLUSIONS

According to the data of 100 case histories of patients with RA the analysis of the use of GCs, NSAIDs and the gastroprotective drug prevention of complications associated with their use has identified compliance of prescriptions with the provisions of the updated national unified clinical protocol of 2014, as well as the EULAR in taking GCs and NSAIDs in RA. These prescriptions were conducted taking into account risk factors for development of side effects associated with administration of GCs and NSAIDs, the presence of concomitant diseases in patients, as well as according to the regimens specified in UCPMC RA and in compliance with the algorithm of the rational choice of NSAIDs for RA.

It has been determined that for the levels of prescriptions of GCs and NSAIDs set the gastroprotective drug prevention of complications associated with their use in the rheumatology department was carried out in compliance with the provisions of UCPMC RA and EULAR.

The results obtained indicate a high level of compliance by practitioners of a healthcare institution with the recommendations of the current clinical protocol of treatment of rheumatoid arthritis, and it will allow both preventing in advance possible undesired effects of using GCs and NSAIDs and reducing the costs of their correction.

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ОЦІНКА ВІДПОВІДНОСТІ ФАРМАКОТЕРАПІЇ СТАЦІОНАРНОГО ЕТАПУ ЛІКУВАННЯ РЕВМАТОЇДНОГО АРТРИТУ ПОЛОЖЕННЯМ ГАЛУЗЕВИХ СТАНДАРТІВ

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Ключові слова: ревматоїдний артрит; стаціонарний етап лікування; частотний аналіз; гастропротекторна медикаментозна профілактика

Постійний моніторинг стаціонарного етапу лікування є необхідним підходом до підвищення якості фармакотерапії та оптимізації витрат на її реалізацію таких високовартісних у лікуванні захворювань як ревматоїдний артрит (РА). За даними 100 історій хвороб пацієнтів з РА проведено аналіз використання глюкокортикоїдів (ГК), нестероїдних протизапальних та протиревматичних засобів (НППЗ) та гастропротекторної медикаментозної профілактики ускладнень, пов'язаних із їх застосуванням на стаціонарному етапі лікування та визначено відповідність призначень положенням оновленого національного клінічного протоколу 2014 р. (УКПМД РА) та рекомендаціям Європейської антиревматичної ліги (EULAR) з використання ГК та НППЗ при ревматоїдних захворюваннях. Сформульовано, що призначення ГК для системного застосування та НППЗ проводилося за зазначеними в УКПМД РА схемами та з дотриманням алгоритму раціонального вибору НППЗ при РА. Визначено, що при встановлених рівнях призначень ГК та НППЗ гастропротекторна медикаментозна профілактика ускладнень, пов'язаних із їх вживанням у ревматологічному відділенні, виконувалась належним чином та за рекомендаціями УКПМД РА та EULAR. Встановлено високий ступінь дотримання практикуючими лікарями закладу охорони здоров'я положень діючого УКПМД РА, що дозволить як завчасно попереджати можливі небажані наслідки використання ГК та НППЗ, так і зменшувати витрати на їх корекцію.

ОЦЕНКА СООТВЕТСТВИЯ ФАРМАКОТЕРАПИИ СТАЦИОНАРНОГО ЭТАПА ЛЕЧЕНИЯ РЕВМАТОИДНОГО АРТРИТА ПОЛОЖЕНИЯМ ОТРАСЛЕВЫХ СТАНДАРТОВ

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Ключевые слова: ревматоидный артрит; стационарный этап лечения; частотный анализ; гастропротекторная медикаментозная профилактика

Постоянный мониторинг стационарного этапа лечения является необходимым условием повышения качества фармакотерапии и оптимизации затрат на ее реализацию таких дорогостоящих в лечении заболеваний как ревматоидный артрит (РА). По данным 100 историй болезни пациентов с РА проведен анализ использования глюкокортикоидов (ГК), нестероидных противовоспалительных средств (НПВС) и гастропротекторной медикаментозной профилактики осложнений, связанных с их применением на стационарном этапе лечения и определены соответствия назначений положениям обновленного национального клинического протокола 2014 (УКПМП РА) и рекомендациям Европейской антиревматической лиги (EULAR) по использованию ГК и НПВС при ревматоидных заболеваниях. Сформулировано, что назначение ГК для системного применения и НПВС проводилось по указанным в УКПМП РА схемам и с соблюдением алгоритма рационального выбора НПВС при РА. Определено, что при установленных уровнях назначений ГК и НПВС гастропротекторная медикаментозная профилактика осложнений, связанных с их употреблением в ревматологическом отделении, выполнялась должным образом и по рекомендациям УКПМП РА и EULAR. Установлен высокий уровень соблюдения практикующими врачами учреждения здравоохранения положений действующего УКПМП РА, что позволит как заблаговременно предупреждать возможные нежелательные последствия использования ГК и НПВС, так и уменьшать затраты на их коррекцию.

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VEN AND FREQUENCY ANALYSIS OF THE QUALITY OF PHARMACOTHERAPY OF PATIENTS WITH CHRONIC HEPATITIS

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Key words: drugs for the treatment of chronic hepatitis; analysis of the quality of treatment

VEN and frequency analysis were used to analyze the quality of pharmacotherapy of 79 patients with chronic hepatitis (CH) who were treated in a healthcare institution (HCI) in the city of Dnipropetrovsk in 2015. It has been found that pharmacotherapy at the HCI corresponded to main areas of the treatment specified in the clinical protocol of medical care (CPMC) to patients with CH. It has confirmed the rationality of drug prescriptions. However, a significant number of prescriptions per a patient (on average 8.9 drugs) indicates the polypharmacy in this department of the HCI. Moreover, according to the results of the formal VEN analysis a significant number of drugs with the index N (non-essential drugs) has been determined; it indicates the need for correction of drug prescription by doctors at this HCI in accordance with the current science-based medical regulations – the National Drug Formulary of Ukraine (the 7th edition) and the CPMC to patients with CH – by reducing prescriptions of non-essential drugs that are not included in these regulations. Today, being developed 11 years ago, the CPMC to patients with CH needs to be updated since it does not meet modern requirements to the current science-based medical practice guidelines that allow making the best clinical decisions in favour of the patient in accordance with the requirements of evidence-based medicine.

Chronic liver diseases are one of the most acute problems of modern gastroenterology. Annually 5% of the world population that exceeds 3 billion people suffer from chronic hepatitis (CH) [2]. In Ukraine, for the past 10 years, the prevalence of CH increased by at least 2.5 times [8]. The above facts demonstrate the importance of the problem of timely diagnosis and pharmacotherapy of hepatitis to improve organization of the specialized medical care, which has not only medical, but also social and economic significance [10].

The results of research and practical medicine show that patients with CH are at high risk of progression of the disease in liver cirrhosis and hepatocellular carcinoma [9]. Cirrhosis of the liver is one of the major causes of death of the population and occupies the 4th place in the structure of causes of death in US men over 40 [6]. In recent years in Ukraine there is a tendency to increase in morbidity and mortality from liver cirrhosis. This situation calls for the optimization of treating patients in healthcare institutions (HCI) by assessing the compliance of the CH pharmacotherapy with regulatory requirements of the Ministry of Health of Ukraine, i.e. by evaluating the quality of pharmacotherapy.

The aim of the study is to analyze the quality of the CH pharmacotherapy in patients in a hospital using VEN and frequency analysis in order to assess how well the pharmacotherapy has been conducted, or whether it corresponds to the current level of medical science and practice.

Materials and Methods

To achieve this goal it was necessary to perform the following tasks: 1) to conduct a retrospective analysis of the medication administration records of patients with chronic hepatitis; 2) to determine the frequency of prescriptions of drugs to patients with CH; 3) according to the results of the formal VEN analysis to assess the compliance of the CH therapy with the regulatory requirements of medical and technological documents of the Ministry of Health of Ukraine: the National Drug Formulary (NDF) and the clinical protocol of medical care (CPMC) to patients with CH [4] and comorbidities. Upon condition that the drug is recommended for the treatment of this disease by the regulation, the index V (vital) will be assigned to it, and in case of the absence of the drug in the regulation – the index N (non-essential) [5]. From medical and technological regulations the NDFU (7th edition, 2015) and the CPMC to patients with CH [4] and other CPMC to patients with comorbidities were used in the study.

The retrospective clinical and economic analysis of prescriptions was conducted on the basis of

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79 case histories of patients with CH, who during 12 months (January – December 2015) were treated in the Department of Gastroenterology of one of the HCI in the city of Dnipropetrovsk.

Results and Discussion

The main diagnosis in 66 patients is chronic hepatitis of the non-viral etiology and in 13 patients – chronic toxic hepatitis. Hereinafter, we combine both names of the disease under the single term "chronic hepatitis" (CH). The age of patients with CH ranged from 16 to 82 (79 patients included 35 women and 44 men). The average period of stay of the patient in the hospital was 16 days. In the case histories studied the following concomitant diagnoses, except for CH, were indicated: chronic cholecystitis (57% of patients), chronic pancreatitis (56% of patients), gastroduodenitis (15.2% of patients), hepatic encephalopathy (11.4% of patients), GERD (6.4% of patients), and ulcerative colitis (3.8% of patients).

According to recommendations of the CPMC to patients with CH (Annex to the Order of the Ministry of Health No. 271 dated 13.06.2005) the CH therapy should be aimed at elimination of toxins from the body due to introduction of detoxification solutions (Rheopolyglucin, Rheosorbilact, 5% glucose solution, etc.); normalization of the gastrointestinal tract through the prescription of probiotics, enterosorbents, enzyme drugs and vitamins; restoration of the liver function by prescribing hepatotropic drugs and maintaining a diet (diet No. 5) excluding fried, salted, pickled, fatty and spicy dishes.

The analysis of case histories of patients with CH showed that 118 trade names (TNs) of drugs and 12 dietary supplements were prescribed to patients. The ratio of foreign and domestic drugs was 2:1. All drugs were referred to 38 INNs and 35 pharmacological groups. To treat the underlying disease 43 TNs assigned to 8 pharmacological groups were used from all drugs prescribed. To treat comorbidities 87 TNs of drugs from 27 pharmacological groups were prescribed to patients.

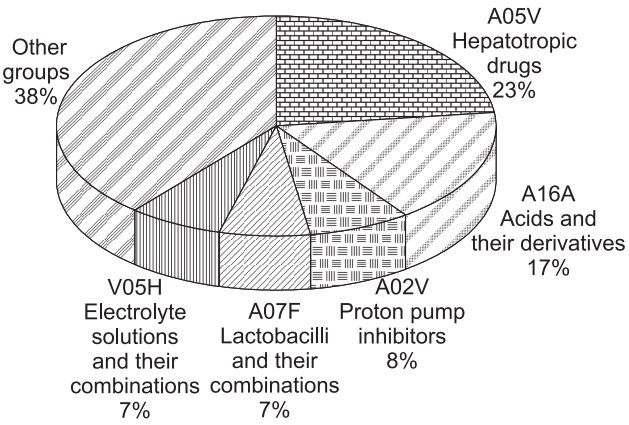

Fig. 1. Leaders by prescription among the ATC groups

During the study period 700 prescriptions of drugs to all patients with CH were registered in this department; it was an average of 8.9 drugs per a patient and indicating the polypharmacy. According to recommendations of the CPMC to patients with CH (Annex to the Order of the Ministry of Health No. 271 dated 13.06.2005) [4], 4-5 INNs of drugs are used for pharmacotherapy of the underlying disease that can be characterized as pharmacotherapy, which corresponds to the WHO requirements.

In this department the prevailing areas of therapy of patients with CH were detoxification therapy (salt, detoxification solutions, glucose solutions) and pathogenetic therapy of the underlying disease (vitamins, probiotics, enterosorbents, hepatotropic drugs), which corresponded to the CPMC to patients with CH applicable at the time of study. The prevailing areas of pharmacotherapy of the concomitant gastroenterological disease were proton pump inhibitors for chronic cholecystitis and pancreatitis (Nolpaza, Controloc). Fig. 1 shows the proportion of each pharmacological group of drugs (%) in the total number of prescriptions to patients with CH for 5 top leaders. The results of frequency analysis showed that the doctors in the department often preferred imported drugs as most TNs of leading drugs by the frequency of prescriptions were of foreign manufacturers.

Fig. 2 shows 10 top leaders among TNs by the frequency of prescription in the HCI. Among them the majority was used in the regimens of the complex therapy of patients diagnosed with CH (Hepa-Merz, Cytoflavin, 5% glucose solution, Phosphogliv, Hepadif, Lacium, Ursolisin), it was consistent with the CPMC data. But taking into account that the CPMC to patients with TH was drawn up 11 years ago (2005) today it does not meet the current requirements to science-based medical information, which allows making the best clinical decisions in favour of the patient. Current requirements of evidence-based medicine provide for continuous improvement of measures for diagnosis, treatment and prevention of diseases. For this purpose, it is necessary to introduce a new improved CPMC to patients suffering from chronic hepatitis of the non-viral etiology, and it should include methods of diagnosis and pharmacotherapy of hepatitis caused by drug-induced injury and hepatitis caused by injury from toxic substances (e.g., benzene, lead, pesticides, etc.). The new unified CPMC to patients suffer-

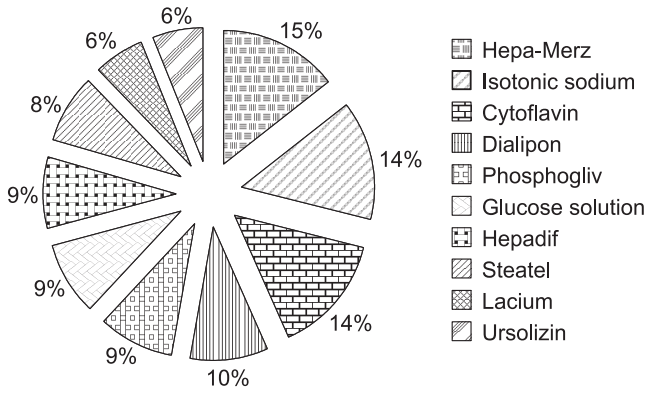

Fig. 2. The 10 top leaders of TN by the frequency of prescription

ing from chronic hepatitis of the non-viral etiology should be developed in accordance with the current requirements of medical and technological documents that will help the doctor to act effectively in a particular clinical situation, thus avoiding inefficient and error procedures. The new protocol should contain the classified information about the latest methods of pharmacotherapy of patients with CH caused by drug-induced injury and toxic substances, INNs of drugs for pharmacotherapy of CH, their course doses and dosage forms, as well as criteria for the treatment efficacy evaluation. The use of this approach for the treatment of patients is recommended by the clinical guidelines of the American College of Gastroenterology, which in 2014 issued the clinical guidelines for the diagnosis and treatment of drug-induced liver injuries (Drug-Induced Liver Injury Guidelines) [7].

The formal VEN analysis of the prescribed drugs was conducted to assess the compliance of the therapy of patients with CH with the regulatory requirements of medical and technological documents. According to the results of VEN analysis conducted using clinical protocols of medical care to patients it was found that 28 of 38 INNs of drugs (73.68%) were referred to the group V – vital and recommended for use in the pharmacotherapy of the underlying disease and comorbidities. 10 INNs of drugs (26.32%) and dietary supplements were absent from the CPMC for the pharmacotherapy of the underlying disease and comorbidities.

According to the results of the formal VEN analysis conducted using the NDFU it was found that most of all TNs of drugs prescribed to patients with CH, i.e. 67.0%, were present in this regulation. 39 TNs of drugs (33.0%) and 12 dietary supplements were absent from the NDFU (7th edition). Out of 39 TNs of drugs that received the index N according to the NDFU (without the evidence base) 15 TNs of drugs were used for the pharmacotherapy of CH in accordance with the current CPMC indicating the lack of conformity between the regulation and current approaches to the treatment of CH, and therefore, it needs to be updated.

The particular attention was drawn to drugs that were not included in both regulations. The following 14 TNs of drugs (11.9%) were referred to them: Osteoarteaze Max (a drug for the treatment of musculoskeletal disorders), Riboxin, Metamax (antiarrhythmic agents of class IB), Dibicor, Mildronate, Mexicor (cardiac drugs), Cyclo-3 fort, L-lysine aescinat (angioprotectors), Traumeel S (homeopathic remedy), Steatel (amino acids and their derivatives), Canephron (complex herbal preparation used in urology), Somaxon, Ceraxon, Vinpocetine (medicines with the neuroprotective effect) and dietary supplements (Gepaval, Gepatomax, Livker, Gepazil, Gynolen, Probiz, Rotabiotic, Forsliv, Selen-Aktiv, Betargin, Vidzhaysar, Forsal). Most of these drugs belong to metabolic ones and can maintain the liver function to a certain extent, but today the level of evidence of the efficacy of these drugs is insufficient (C and D levels) to be included in the treatment regimen. The sufficient levels of evidence of the clinical efficacy for drugs in accordance with the current requirements are considered to be A and B levels [1].

Thus, a significant amount of drugs with the index N according the results of VEN analysis indicates the need for correction of prescribing drugs by doctors of this HCI in accordance with the NDFU and the CPMC by reducing non-essential drugs that are not included in the regulatory medical and technological documents. Considering the fact that in Ukraine the NDFU is a modern document and is updated every year, and the CPMC to patients with CH is a significantly outdated document, it was necessary to carry out the pharmacotherapy of patients with CH in this HCI substantially corresponding to the requirements of the NDFU. Unfortunately, the results of the analysis indicate imperfect therapy of patients with CH at the HCI in Dnipropetrovsk.

CONCLUSIONS

1. Pharmacotherapy of patients with CH by the prescribed pharmacotherapeutic groups corresponded to the main areas of the treatment specified in the CPMC. It has confirmed the rationality of most prescriptions, but the average number of prescriptions per a patient is 8.9 TNs, indicating the polypharmacy in this department of the hospital.

2. Being developed 11 years ago, the CPMC to patients with CH needs to be updated since it does not meet modern requirements to the current science-based medical practice guidelines (does not contain information concerning INNs of the drugs, their course doses and dosage forms, does not contain criteria for the treatment efficacy evaluation, and it is not con-

sistent with the requirements of evidence-based medicine).

3. Most drug prescriptions for the pharmacotherapy of patients with CH were drugs included in the NDFU of the 7th edition (67.0%) and the Ukrainian CPMC to patients with the underlying disease and comorbidities (73.68%). It has confirmed the rationality of most drug prescriptions from the clinical point of view, but indicates the need for correction of the CH pharmacotherapy at the HCI in Dnipropetrovsk.

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VEN ТА ЧАСТОТНИЙ АНАЛІЗ ЯКОСТІ ФАРМАКОТЕРАПІЇ ХВОРИХ НА ХРОНІЧНИЙ ГЕПАТИТ

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Ключові слова: лікарські засоби для лікування хронічного гепатиту; аналіз якості лікування

Для проведення аналізу якості фармакотерапії 79 хворих на хронічний гепатит (ХГ), які проходили лікування протягом 2015 року у закладі охорони здоров'я (ЗОЗ) м. Дніпропетровська, використовували VEN і частотний аналіз. Встановлено, що фармакотерапія в ЗОЗ за призначуваними фармакотерапевтичними групами відповідала основним напрямкам лікування, зазначеним у клінічному протоколі надання медичної допомоги (КПНМД) хворим на ХГ, що підтверджує раціональність лікарських призначень. Але значна кількість призначень на 1 хворого (в середньому 8,9 ЛЗ) свідчить про поліпрагмазію в даному відділенні ЗОЗ. Крім того, за результатами формального VEN-аналізу встановлена значна кількість ЛЗ з індексом N (другорядні засоби), що вказує на необхідність корекції призначень ЛЗ лікарями даного ЗОЗ відповідно до науково-медичних нормативних документів: Державного формуляру лікарських засобів України (7 випуск) і КПНМД хворим на ХГ шляхом зменшення призначень другорядних ЛЗ, що до них не входять. На сьогоднішній день КПНМД хворим на ХГ потребує оновлення, оскільки він розроблений 11 років тому і не відповідає сучасним вимогам до даних науково-медичних нормативних документів, які дозволяють приймати оптимальні клінічні рішення на користь пацієнта згідно з вимогами доказової медицини.

VEN И ЧАСТОТНЫЙ АНАЛИЗ КАЧЕСТВА ФАРМАКОТЕРАПИИ БОЛЬНЫХ С ХРОНИЧЕСКИМ ГЕПАТИТОМ

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Ключевые слова: лекарственные средства для лечения хронического гепатита; анализ качества лечения

Для проведения анализа качества фармакотерапии 79 больных хроническим гепатитом (ХГ), проходивших лечение в 2015 году в учреждении здравоохранения (УЗ) г. Днепропетровска, использовали VEN и частотный анализ. Установлено, что фармакотерапия в УЗ по назначаемым фармакотерапевтическим группам отвечала основным направлениям лечения, указанным в клиническом протоколе оказания медицинской помощи (КПОМП) больным ХГ, что под-

тверждает рациональность врачебных назначений. Но значительное количество назначений на 1 больного (в среднем 8,9 ЛС) свидетельствует о полипрагмазии в данном отделении УЗ. Кроме того, по результатам формального VEN-анализа установлено значительное количество ЛС с индексом N (второстепенные средства), что указывает на необходимость коррекции назначений ЛС врачами данного УЗ в соответствии с научно-медицинскими нормативными документами: Государственным формуляром лекарственных средств Украины (7 выпуск) и КПОМП больным ХГ путем уменьшения назначений второстепенных ЛС, которые в них не входят. На сегодняшний день КПОМП больным ХГ нуждается в обновлении, поскольку он разработан 11 лет назад и не соответствует современным требованиям к данным научно-медицинским нормативным документам, которые позволяют принимать оптимальные клинические решения в пользу пациента в соответствии с требованиями доказательной медицины.

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THE CLINICAL AND ECONOMIC ANALYSIS OF PHARMACEUTICAL PROVISION OF PATIENTS WITH DEPRESSIVE DISORDERS IN HOSPITAL ENVIRONMENT

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Key words: depression; clinical and economic analysis; pharmaceutical provision of patients with depressive disorders

The results of the clinical and economic analysis of pharmaceutical provision of patients with depressive disorders in the departments of the specialized healthcare institution in 2015 are presented. It has been found that drugs for the pathogenetic treatment of depression account for the greatest number of medical prescriptions in the structure of drug consumption. Thus, according to the results of studies the greatest number of prescriptions and the highest amount of drug consumption are per three antidepressants. More than half of the resource has been spent on consumption of drugs that are essential by the requirements of the regulatory framework regulating the issues of medical care to patients with depressive disorders. Taking into account the fact that a significant number of the patients who underwent inpatient treatment had a recurrent nature of the disease further pharmacoepidemiological studies of the drug consumption should be expedient, namely determination of the rationality of prescribing drugs with the antidepressant action using the ATC-DDD methodology.

The urgency of the problem of depressions is caused by their prevalence, significant influence on the quality of life, social functioning of a person in almost all areas of life: employment, family, social contacts. Depression refers to diseases that are accompanied by severe medical and social consequences, including disability, suicide, and economic losses. Indicators of disability in depressive disorders exceed similar indicators in cerebrovascular and cardiovascular diseases. According to the WHO protocol by 2020 depression will occupy the second place after ischemic heart disease among the causes of disability. In accordance with the existing standards of medical care of patients with depression the main method of treatment is pharmacotherapy with antidepressants of the latest generation [6]. The current standards of medical care of patients with depression include prescriptions of antidepressants of the last generation. Modern medicines have a sufficient level of evidence of efficacy and safety, but they are preferably expensive. The last fact should be considered for the patients who require treatment for a long time. Development of activities to provide availability of the treatment of patients based on the results of the clinical and economic analysis (CEA) is of particular relevance in this case.

Therefore, the aim of this work was to carry out the comprehensive clinical and economic analysis of the state of pharmaceutical provision for patients with depressive disorders who underwent inpatient treatment in a specialized healthcare institution.

Materials and Methods

The object of the research was the data of 196 medication administration records of the patients with depressive disorders treated in the departments of the healthcare institution in 2015.

CEA of pharmaceutical provision of patients with depressive disorder ABC-, VEN- and frequency analysis were carried out according to the methods developed and tested by domestic scientists of the Department of Organization and Economics of Pharmacy of the NUPh under the supervision of professor A.S.Nemchenko. First of all, frequency analysis involves determining the frequency of prescriptions of different types of drugs according to the data of medication administration records. According to the ABC analysis all drugs were divided by the level of their investment into three groups: A – the most expensive drugs (80.0% of the total drug consumption for a certain period of time); B – average-cost drugs (15.0%); C – low-cost drugs (5.0%) [7]. The formal approach to determine the possibility of including drugs in groups (VEN-analysis) was used. Thus, group V included drugs that were the part of the National List of essential medicines and medical devices (decree of CMU from 25.03.2009 No. 333, Budget list of drugs (decree of CMU from 05.09.1996 No. 1071 "On the procedure of drug purchase by healthcare institutions financed from the budget" amended in accordance with the Orders of MPH of Ukraine dated from 27.08.2010 No. 631, 26.04.2011, No. 170, 5.03.2012, No. 79, 7.03.2013 No. 105, the State Formulary of drugs of the VIIth edition and unified clinical protocol of the primary, secondary (specialized) and tertiary (highly specialized) medical care "Depression

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(mild, moderate, severe depressive episodes without the somatic symptom or with the somatic syndrome, recurrent depressive disorder, dysthymia" (Order of MPH of Ukraine dated from December 25, 2014 No. 1003). Group E included the names of drugs, which were absent in the National List of essential drugs and medical devices and present in all other documents, and group N included all the other names of drugs [4, 5]. To calculate the amount of expenditure the data from the accounting documentation of the healthcare institution were used.

Processing of statistical data was carried out using the Microsoft Office Excel 2010 tabular processor and standard programs of applied statistical analysis Statistica 6.0.

Results and Discussion

At the first stage of our studies the analysis of the socio-demographic structure of patients according to various parameters (age, gender, social status, place of residence, the presence of comorbidities) was conducted. The age of the patients hospitalized was from 28 to 60 years. It was found that, in general, the patients were mostly women (62.2%), and it was consistent with the literature data. A significant number of patients (81.3%) had the recurrent nature of the disease; only 7 (3.57%) patients underwent in-patient treatment for the first time. At the place of permanent residence urban residents (73.98% of the total number of patients) comprised the vast majority. Among the patients, the proportion of employees was 41.67%; the percentage of the most socially vulnerable people (pensioners, temporarily unemployed, I-II group disabled) was 53.1%. The state almost of all patients was accompanied with concomitant comorbidity diseases.

According to the data from medication administration records the analysis of the frequency of drug prescriptions was carried out. It was found that doctors made 1078 prescriptions of 60 names of drugs according to INN ("International Nonproprietary Name"), and there were 89 drugs by trade names.

The results of frequency analysis of prescriptions obtained allow to assert that patients with depressive disorders were primarily prescribed drugs with the pathogenetic action. Antidepressant drugs have the largest number of medicinal prescriptions. Moreover, according to INN three drugs, namely sertraline (69 prescriptions or 35.2% of all patients), fluoxetine (59 prescriptions – 30.1%), fluvoxamine (41 prescriptions – 20.92%) had the highest rates of prescriptions. Taking into account the clinical condition of the patient such drugs as diazepam (39 prescriptions – 18.84%), galoperidol (33 prescriptions – 16.84%), clozapine (31 prescriptions – 15.82%), oxazepam (29 prescriptions – 14.8%) were prescribed according to INN. In general, the group of drugs "Drugs that affect the nervous system" included 537 prescriptions or 49.81% of their total number. According to INN the number of drugs of the pharmacotherapeutic group specified was 25 or 41.7% of the range. Correction of somatic autonomic disorders also required prescription of various drugs (35 or 58.3% of the total range).

The next stage of the research was to rank drugs by actual drug prescription and their distribution by the ABC groups. Group A contained drugs, which consumption was 102912.38 UAH, or 79.55% of the total consumption, group B – 20039.13 UAH (15.49%), and group C – 6416.67 UAH (4.96%), respectively.

Group A included 10 drugs according to INN (16.7% of the range studied), its bulk were drugs affecting the nervous system. According to INN group B was formed of 26 drugs (43.3%), belonging to different pharmacological groups, and group C consisted of 24 drugs (40.0%). It should be noted that group C included drugs intended for the treatment of comorbidity in patients with depressive disorders.

An important characteristic of the pharmaceutical provision state of patients is that in the structure of drug consumption the names used in pathogenetic treatment of depressive disorders dominate. The consumption indicator calculated according to this group is 90208.42 UAH (69.73% of the total consumption indicator).

According to the results of VEN-analysis it was found that most drugs (43.3% of the range) were important. The proportion of drugs with the status N is 33.33%, for them 4.96% of the costs associated with the pharmaceutical provision of patients was spent. Thus, there is a need to find the ways for further optimization of the costs for non-essential drugs.

The results of the complex CEA have proven that the largest share of expenditure (51.89%) is related to the pharmaceutical provision of patients with depressive disorders. According to INN it comprises 5 drugs, which are the most expensive and essential; the total number of prescriptions is 247, or 22.91% of all prescriptions.

The cost parameters of the annual drug consumption calculated per a patient were from 237,15 UAH to 1398,47 UAH. Moreover, medical prescriptions had an individual character and were in agreement with clinical guidelines. These significant variations in cost parameters of drug consumption per a patient determines the feasibility of further pharmacoeconomic studies aimed at selecting optimal treatment regimens for patients with depressive disorders.

CONCLUSIONS

1. It has been found that while patients underwent the treatment in the departments of a specialized healthcare institution 60 drugs were used according to

INN, and 1078 drug prescriptions were made by doctors.

2. Frequency analysis of medical prescriptions has showed that the greatest number of prescriptions (537 prescriptions or 49.81% of the total prescriptions) is of the group "Drugs that affect the nervous system", the number of drugs according to INN is 25 or 41.7% of the range.

3. The total rate of consumption for patients with depressive disorders was 129368.17 UAH. According to the ABC analysis group A (the most expensive) includes 10 drugs that affect the nervous system according to INN.

4. VEN-analysis has showed that among the range of the drugs prescribed to the patients with depressive disorders the share of the vital drugs is 13.3%, essential drugs – 53.3% and non-essential drugs – 33.3%.

5. An important direction for future research is to conduct pharmacoepidemiological studies of drug consumption, namely determination of the rationality of prescribing drugs with the antidepressant action using the ATC-DDD methodology.

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КЛІНІКО-ЕКОНОМІЧНИЙ АНАЛІЗ ФАРМАЦЕВТИЧНОГО ЗАБЕЗПЕЧЕННЯ ХВОРИХ НА ДЕПРЕСИВНІ РОЗЛАДИ В УМОВАХ СТАЦІОНАРУ

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Ключові слова: депресія; клініко-економічний аналіз; фармацевтичне забезпечення хворих на депресивні розлади

Представлені результати клініко-економічного аналізу фармацевтичного забезпечення хворих на депресивні розлади у відділеннях спеціалізованого закладу охорони здоров'я у 2015 році. Встановлено, що у структурі споживання препаратів найбільша кількість лікарських призначень припадає на лікарські засоби для патогенетичного лікування депресії. Так, за результатами досліджень на три лікарських засоби антидепресивної дії припадає найбільша кількість призначень та найбільші витрати. Більше половини ресурсів було витрачено на споживання препаратів, необхідних за вимогами нормативно-правової бази, яка регулює питання надання медичної допомоги хворим на депресивні розлади. Враховуючи той факт, що значна кількість хворих, які перебували на стаціонарному лікуванні, має рецидивуючий характер перебігу захворювання, у подальшому необхідні фармакоепідеміологічні дослідження споживання лікарських засобів, а саме визначення раціональності призначень лікарських засобів антидепресивної дії за допомогою АТС-DDD методології.

КЛИНИКО-ЭКОНОМИЧЕСКИЙ АНАЛИЗ ФАРМАЦЕВТИЧЕСКОГО ОБЕСПЕЧЕНИЯ БОЛЬНЫХ С ДЕПРЕССИВНЫМИ РАССТРОЙСТВАМИ В УСЛОВИЯХ СТАЦИОНАРА

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Ключевые слова: депрессия; клинико-экономический анализ; фармацевтическое обеспечение больных с депрессивными расстройствами

Представлены результаты клинико-экономического анализа фармацевтического обеспечения больных с депрессивными расстройствами в отделениях специализированных учреждений здравоохранения в 2015 году.

Установлено, что в структуре потребления препаратов наибольшее количество врачебных назначений приходится на лекарственные средства для патогенетического лечения депрессии. Так, по результатам исследований на три лекарственных средства антидепрессивного действия приходится наибольшее количество назначений и наибольшие затраты. Более половины ресурсов было потрачено на потребление препаратов, которые являются необходимыми по требованиям нормативно-правовой базы, регулирующей вопросы оказания медицинской помощи больным с депрессивными расстройствами. Учитывая тот факт, что значительное количество больных, которые находились на стационарном лечении, имеет рецидивирующий характер течения заболевания, в дальнейшем необходимы фармакоэпидемиологические исследования потребления лекарственных средств, а именно определение рациональности назначений лекарственных средств антидепрессивного действия с помощью ATC-DDD методологии.

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ANALYSIS OF ECONOMIC AFFORDABILITY OF THE ANTIHYPERTENSIVE THERAPY FOR THE TREATMENT OF HYPERTENSION

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Key words: hypertension; affordability ratio; coefficient of the solvency adequacy; first line antihypertensive drugs

Hypertension (HTN) is a common disease, which main manifestation is high blood pressure (BP). Nowadays, HTN is found in 30-40% of the adult population of the world. The prevalence of HTN in the population increases with age. Among people aged 18-29 years old the prevalence of HTN is 4%; aged 50-59 years old – 44%; among people aged 60-69 years old – 54%, and aged 70 and older – 65%. The aim of this study was to evaluate the range and economic affordability of antihypertensive drugs. The analysis has shown that the range of the first line antihypertensive drugs includes 35 INNs of drugs represented by 570 TNs. Most part of the market – 68.5% is taken by foreign drugs and only 31.1% – by domestic drugs. The range of antihypertensive drugs includes drugs of different generations: in addition to well-known drugs there are also new ones that have significant advantages both in terms of clinical efficiency and safety. The analysis of economic affordability has shown that the vast majority of drugs are highly affordable for the Ukrainian consumers, and their total number when calculated at the maximum price is 54.3% (19 INNs) of all drugs presented at the Ukrainian pharmaceutical market. The share of drugs with average affordability is 37.1% (13 INNs); it allows the average citizen of Ukraine taking drugs during the entire treatment of HTN without experiencing a significant impact on his/her own budget, and only 8.6% (3 INNs) are drugs with low affordability. But drugs with low affordability are modern and have significant advantages when used in clinical practice compared to available analogs.

Hypertension (HTN) is a common disease, which main manifestation is high blood pressure (BP) often combined with regional vascular tone disorders in the absence of causal relationship with the primary organic damage of any organs or systems. HTN is characterized by staging in development of symptoms. In more than 90% of cases BP can be idiopathic (primary, essential), and in this case it is called HTN. In 5-10% of cases, HTN has an established cause (secondary HTN) [1, 2].

Increase in systolic BP over 140 mm Hg or diastolic over 90 mm Hg should be understood as HTN. There are the following HTN stages: I – no objective manifestations of organic changes in vital organs; II – the presence of objective manifestations of organic changes in vital organs (left ventricular hypertrophy, generalized or focal narrowing of the retinal artery, proteinuria or hypercreatinemia, which are not initially associated with kidney diseases); III – HTN complications appear (myocardial infarction, chronic heart failure, ischemic and hemorrhagic stroke, renal failure [3, 4, 5].

According to statistics, 12,157,099 of hypertensive patients, i.e. 26.4% of the adult population, were recorded in Ukraine in 2013. The prevalence of the disease is 26,793.9 per 100 thousand of the population, including new cases – 8,978.8 persons. There has been a steady increase in the prevalence of HTN – more than doubled as compared to 1998 and by 170% – compared to 2000. The prevalence of HTN among circulatory diseases (CD) in adults is 46.8%, i.e. almost half of patients with CD have high BP [7, 9].

In Ukraine, according to epidemiological studies, the age-adjusted prevalence rate of HTN in the urban population is 29.6% for both men and women. In the rural population the prevalence of HTN is higher – 36.3%, including 37.9% – among men, and 35.1% – in women.

Based on data of the Ministry of Health, when analyzing the HTN structure by the level of BP, 50% of patients had arterial hypertension (AHT) of the 1st level, every third – AHT of the 2nd level, and every fifth – AHT of the 3rd level [7].

Among those with high blood pressure 67.8% of rural and 80.8% of urban residents are aware of the presence of the disease, 38.3% and 48.4% are treated, and the treatment efficiency is 8.1% and 18.7%, respectively. Thus, the situation as to the AHT monitoring is unsatisfactory in both rural and urban population, but it is extremely unfavorable in rural areas [6].

Based on the data from a large-scale meta-analysis it has been confirmed that the first line drugs for treating HTN are diuretics (thiazide and thiazide-like) (the main mechanism of action of thiazide diuretics is the rapid elimination of sodium and potassium ions, thus achieving maximum excretion of liquid from the body that leads to decrease of BP), angiotensin-converting-enzyme inhibitors

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Table 1

Groups of antihypertensive drugs, their International Nonproprietary Names (INNs) and the number of trade names (TNs) presented at the Ukrainian pharmaceutical market

Group of antihypertensive drugs	INNs and the number of TNs
Beta-blockers (C07A) 8 INNs, 143 TNs	Propranolol (4 TNs), metoprolol (23 TNs H), atenolol (12 TNs), betaxolol (3 TNs), bisoprolol (59 TNs), esmolol (1 TN), nebivolol (10 TNs), carvedilol (31 TNs)
Angiotensin-converting-enzyme inhibitors (ACE inhibitors) (C09A) 10 INNs, 172 TNs	Captopril (8 TNs), enalapril (41 TNs), lisinopril (60 TNs), perindopril (10 TNs), ramipril (40 TNs), fosinopril (4 TNs), spirapril (1 TN), moexipril (4 TNs), zofenopril (3 TNs), enalaprilat (1 TN)
Angiotensin II receptor blockers (AA II) (C09D) 6 INNs, 94 TNs	Losartan (34 TNs), eprosartan (1 TN), valsartan (21 TNs), ibesartan (7 TNs), candesartan (13 TNs), telmisartan (18 TNs)
Calcium channel blockers (CCB) (C08C) 9 INNs, 143 TNs	Amlodipine (66 TNs), felodipine (4 TNs), nifedipine (23 TNs), nimodipine (5 TNs), nitrendipine (2 TNs), lercanidipine (10 TNs), lacidipine (2 TNs), verapamil (22 TNs), diltiazem (9 TNs)
Thiazide and thiazide-like diuretics (TD) (C03B) 2 INNs, 18 TNs	Hydrochlorothiazide (3 TNs), indapamide (15 TNs)

(ACE inhibitors) (the mechanism of action of ACE inhibitors is inhibition of angiotensin-converting enzyme, which catalyzes formation of angiotensin II and at the same time stimulates degradation of bradykinin to inactive fragments). The consequence of reducing the concentration of angiotensin II in the circulatory bed and tissues is inhibition of a number of its effects, including BP lowering. Calcium channel blockers are also the first line drugs; calcium antagonists block the entry of calcium ions into vascular and myocardial cells, reduce the conversion of energy associated with phosphates into mechanical work, thus decreasing the ability of the myocardium to develop the strain, and reduce its contractility. The effect of these drugs on the wall of coronary vessels leads to their expansion (the antispasmodic effect) and increase in the coronary blood flow, and impact on peripheral arteries – to systemic arteriolar dilation, reduction of peripheral resistance, lowering of systolic and diastolic BP (the hypotensive action). Other drugs for treating HTN are angiotensin II receptor blockers (the mechanism of action is to block binding of angiotensin II to receptors, and it leads to vasodilation, reduction of aldosterone release, and sodium reabsorption in the kidneys; these mechanisms provide the antihypertensive effect) and β1-blockers (the mechanism of action is blocking beta-adrenergic receptors of the heart, resulting in decreased heart rate (HR) and decreased myocardial contractility. This leads to decrease in cardiac output, decreased myocardial contractility, inhibition of central adrenergic effects (for substances penetrating through BBB), and the antirenin effect of drugs causes decrease in systolic and then diastolic pressure) [7].

The above groups of drugs are considered to be suitable for both the initial and supporting antihypertensive therapy [7].

The availability of a large number of pharmacological drugs for antihypertensive therapy greatly increases the chance of achieving blood pressure control in vast majority of patients. It is important to take into account the proven fact that the BP decrease only by 5-6 mm Hg is associated with reduced mortality due to cardiovascular diseases by 21%, frequency of strokes – by 42% and myocardial infarction – by 14% [6, 7].

The data of evidence-based medicine suggest that the rational antihypertensive therapy significantly improves the prognosis of patients with HTN. Therefore, the aim of this study was to evaluate the cost and economic affordability of antihypertensive drugs. To achieve this goal, it was necessary to solve the following problems:

1. to conduct the analysis of the range of antihypertensive drugs presented at the Ukrainian pharmaceutical market;
2. to assess the economic affordability of the first line antihypertensive drugs for patients.

Materials and Methods

The analysis of the range of domestic and foreign antihypertensive drugs at the pharmaceutical market was conducted based on the data of Morion Pharmstandard Analytical Market Research System [8]. To assess the economic affordability of the antihypertensive therapy the coefficient of the solvency adequacy (Ca.s) showing what percentage of the average wage of the Ukrainian consumer should be spent on the course of treatment with the drug was used. The greater the value of Ca.s is, the less affordable is the drug for the consumer. The coefficient of the solvency adequacy was calculated by the formula:

$$Ca.s = P.c.t./Wa.w. \times 100\%,$$

where: Ca.s – is the coefficient of the solvency adequacy;
P.c.t. – is the cost of treatment;
Wa.w. – is the average wage within the year under study [10].

The value of the average wage was found on the website:

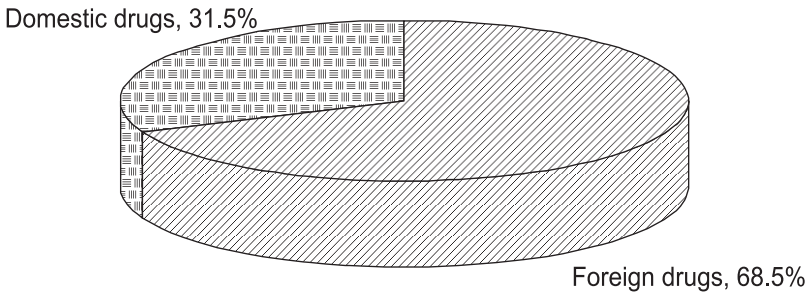

Fig. 1. The ratio of foreign and domestic drugs among the first line antihypertensive drugs

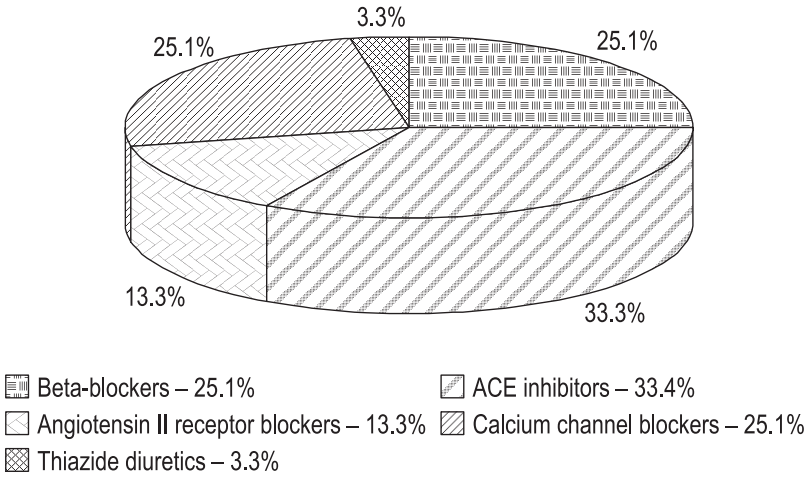

Fig. 2. The proportion of TNs of the first line antihypertensive drugs of different pharmacological groups at the Ukrainian pharmaceutical market

www.ukrstat.gov.ua. The course of treatment for calculations was 30 days.

Results and Discussion

There were 5 groups of first line antihypertensive drugs at the Ukrainian pharmaceutical market (Tab. 1).

The range of antihypertensive drugs has 35 International Nonproprietary Names (INNs) of drugs presented by 570 trade names (TNs). The share of foreign drugs is 68.5%, and domestic drugs – 31.5% (Fig. 1).

The greatest number of TNs of drugs 33.3% is presented in the group of angiotensin-converting-enzyme inhibitors (190 TNs), which leaders are enalapril (41 TNs), lisinopril (60 TNs) and ramipril (40 TNs), the significant share belongs to beta-blockers – 25.1% (143 TNs) and calcium channel blockers (143 TNs) – 25.1%, a slightly lower proportion is taken by angiotensin II receptor blockers – 13.3%, and the lowest share of 3.3% is taken by the group of thiazide diuretics (18 TNs) (Fig. 2).

The next stage of this study was to assess economic affordability of antihypertensive drugs belonging to the standard of medical care of patients with HTN and those present at the Ukrainian pharmaceutical market (Tab. 2).

Based on the data obtained it has been found that all antihypertensive drugs are highly affordable (Ca.s < 5%), except for Felodip and Enap®, by the Ca.s value at the minimum price per the course of treatment (30 days). The coefficient of the solvency adequacy of the most drugs provides availability of the drug and guarantees the sale against the low paying capacity of the population. Felodip belongs to blockers of "slow" calcium channels of dihydropyridines. It reduces the size of myocardial infarction and protects against reperfusion complications. It practically has no negative effects with the minimal effect on the cardiac conduction system. Enap® inhibits angiotensin-converting enzyme, reduces the concentration of angiotensin II and aldosterone in the blood and improves the kallikrein-kinin vasodepressor system functioning. The drug reduces TPR, SBP and DBP. The action begins in 1.5-15 min after intravenous injection, reaches the maximum in 1-4 hours and lasts about 6 hours. These drugs have average affordability, their Ca.s = 5.02% and 7.88%, respectively. These drugs are less affordable, but taking into account the peculiarities of their pharmacological profile they can be used widely in Ukraine.

The Ca.s values calculated by the maximum price show that drugs by 13 INNs are with average affordability (Ca.s < 15%) and by 3 INNs – with low affordability (Ca.s > 15%). The drugs with low affordability include: Diovan (valsartan) (film-coated tablets, 80 mg, No.28 Novartis Pharma (Switzerland); it has a selective antagonistic action with respect to the receptor apparatus of angiotensin II (AT II). Diovan has no active metabolite and does not require biotransformation during the initial passage through the liver. It has high (95%) ability to bind to plasma proteins, primarily albumin. The effect of the dose lasts for up to 24 hours, it increases compliance of patients to therapy. The efficiency does not depend on sex, age and race. Valsartan is not inferior to amlodipine, hydrochlorothiazide and lisinopril by its antihypertensive efficiency and even exceeds the latter by tolerability. The probability of cough when using valsartan is very low due to the lack of impact on ACE, which is responsible for degradation of bradykinin. Comparison of Diovan with ACE inhibitor showed that the incidence of dry cough was significantly lower in patients receiving Diovan than in patients treated with ACE inhibitor (2.6 vs. 7.9%, respectively). The use of this drug is not accompanied by a sharp decrease in blood pressure, or other adverse clinical consequences.

Table 2

Indicators of economic affordability of the first line antihypertensive drugs for 2014

INN	min cost of a package (UAH)	Ca.s min per the course of treatment (30 days)	max cost of a package (UAH)	Ca.s max per the course of treatment (30 days)
Beta-blockers (C07A)				
Propranolol	42.59	1.35	76.11	2.42
Metoprolol	8.71	0.28	197.38	6.27
Atenolol	6.04	0.19	59.16	1.88
Betaxolol	76.33	2.42	183.85	4.19
Bisoprolol	9.61	0.31	104.4	3.3
Esmolol	2,591.32	–	2,591.32	82.27
Nebivolol	47.28	1.5	126.92	4.03
Carvedilol	24.19	0.77	453.29	14.39
Angiotensin-converting-enzyme inhibitors (C09A)				
Captopril	21.56	0.68	124.15	3.94
Enalapril	5.53	0.18	156.12	4.96
Lisinopril	6.41	0.2	498.03	15.81
Perindopril	39.66	1.26	102.75	3.26
Ramipril	27.38	0.87	190.75	6.06
Fosinopril	82.07	2.61	196.28	6.23
Spirapril	115.07	–	115.07	3.65
Moexipril	77.03	2.45	230.13	7.31
Zofenopril	137.4	4.36	178.29	4.66
Enalaprilat	248.2	–	248.2	7.88
Angiotensin II receptor blockers (C09D)				
Losartan	16.11	0.51	261.65	8.31
Eprosartan	122.97	–	122.97	3.9
Valsartan	58.71	1.86	1,126.49	35.76
Ibesartan	57.14	1.81	151.39	4.81
Candesartan	26.37	0.84	254.59	8.08
Telmisartan	39.23	1.25	196.31	6.23
Calcium channel blockers (C08C)				
Amlodipine	8.96	0.28	206.12	6.54
Felodipine	158.24	5.02	309.57	9.83
Nifedipine	3.97	0.13	461.81	14.66
Nimodipine	71.22	2.26	88.14	2.80
Nitrendipine	112.43	3.57	153.95	4.89
Lacidipine	130.58	4.15	140.13	4.45
Lercanidipine	37.85	1.20	95.30	3.03
Verapamil	3.95	0.13	351.92	11.17
Diltiazem	32.39	1.03	139.61	4.43
Thiazide and thiazide-like diuretics (C03B)				
Hydrochlorothiazide	27.52	0.87	115.5	3.67
Indapamide	16.26	0.52	91.42	2.9

Another drug with low affordability presented at our market is Lizinovel (tabl., 10 mg, in blister, No.10, Astrapharm (Ukraine) – ACE inhibitor. Inhibition of the ACE activity leads to reduction of angiotensin II in the blood plasma, decrease in aldosterone release and, as a consequence, lowering of blood pressure in patients with hypertension, and improves the course of heart failure. In patients with essential hypertension decrease of blood pressure is associated with decrease in total peripheral resistance with little change in the heart rate. The hypotensive effect develops in almost an

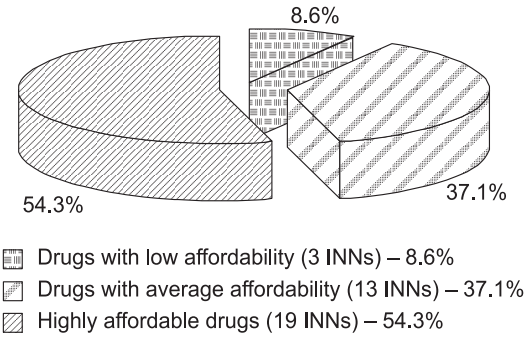

Fig. 3. The ratio of affordability of antihypertensive drugs for the Ukrainian consumers by the value of Ca.s calculated on the basis of maximum prices for drugs

hour after administration and reaches its maximum about 6 hours later. The effect lasts for 24 hours and depends on the dose that increases compliance of the patient. The third drug included in the group of drugs with low affordability is Brevibloc (solution for injections, 10 mg/ml, 10 ml vial, No.5, Baxter AG (Switzerland) – it blocks β1-adrenergic receptors, but unlike other drugs of this group Brevibloc differs in ultrashort duration of action (the absolute therapeutic effect develops within 2 min and terminates in 15-20 min after completing the infusion. $T_{1/2}$ – 9 min), it provides the successful use in acute situations in case of hypertensive crisis, severe arrhythmias and heart surgery. This drug is almost unaffordable for the Ukrainian consumers as Ca.s for it is 82.27%.

According to the data calculated at the maximum price for the drug and the Ca.s value per the course of treatment of 30 days it has been found that 54.3% (19 INNs) of antihypertensive drugs at the Ukrainian pharmaceutical market are taken by highly affordable drugs, 37.1% (13 INNs) – drugs with average affordability and only 8.6% (3 INNs) – drugs with low affordability for the Ukrainian consumers (Fig. 3). But drugs with low affordability are modern and have significant advantages when used in clinical practice compared to available analogs.

CONCLUSIONS

1. The analysis has shown that the range of the first line antihypertensive drugs includes 35 INNs of drugs represented by 570 TNs. Most part of the market – 68.5% is taken by foreign drugs and only 31.1% – by domestic drugs. The range of antihypertensive drugs includes drugs of different generations: in addition to well-known drugs there are also new ones that have significant advantages both in terms of clinical efficiency and safety.

2. The analysis of economic affordability of the first line antihypertensive drugs at the maximum price has shown that the vast majority of drugs are highly affordable for the Ukrainian consumers, and their total number when calculated at the maximum price is 54.3% (19 INNs) of all drugs presented at the Ukrainian pharmaceutical market. The share of drugs with average affordability is 37.1% (13 INNs); it allows the average citizen of Ukraine taking drugs during the entire treatment of HTN without experiencing a significant impact on his/her own budget, and only 8.6 % (3 INNs) are drugs with low affordability. But drugs with low affordability are modern and have significant advantages when used in clinical practice compared to available analogs.

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АНАЛІЗ ЕКОНОМІЧНОЇ ДОСТУПНОСТІ АНТИГІПЕРТЕНЗИВНОЇ ТЕРАПІЇ ГІПЕРТОНІЧНОЇ ХВОРОБИ

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Ключові слова: гіпертонічна хвороба; коефіцієнт доступності; показник адекватності платоспроможності; антигіпертензивні препарати першої лінії застосування

Гіпертонічна хвороба (ГХ) – розповсюджене захворювання, основним проявом якого є підвищення артеріального тиску (АТ). На теперішній час ГХ виявлена у 30-40% дорослого населення країн світу. Поширеність ГХ в популяції з віком збільшується. Серед осіб 18-29 років поширеність ГХ становить 4%; у віці 50-59 років – 44%; серед осіб 60-69 років – 54%, а у віці 70 років і старше – 65%. Метою даної роботи була оцінка асортименту та економічної доступності антигіпертензивних препаратів. У результаті проведеного аналізу було встановлено, що асортимент антигіпертензивних ЛЗ першої лінії застосування налічує 35 МНН препаратів, які представлені 570 ТН. Більшу частину ринку – 68,5% складають ЛЗ закордонного виробництва і лише 31,1% – вітчизняні ЛЗ. Асортимент антигіпертензивних ЛЗ включає препарати різних поколінь: поряд із широко відомими є нові препарати, що мають суттєві переваги як за клінічною ефективністю, так і за безпечністю. Аналіз економічної доступності показав, що переважна більшість препаратів є високодоступними для українського споживача, їх загальна кількість при розрахунку за максимальною ціною складає 54,3% (19 МНН) від усіх представлених ЛЗ на фармацевтичному ринку України. Частка середньодоступних препаратів складає 37,1% (13 МНН), що дає змогу середньостатистичному жителю України приймати ЛЗ протягом усього курсу лікування ГХ, не відчуваючи значного впливу на власний бюджет, і лише 8,6% (3 МНН) є малодоступними ЛЗ. Але малодоступні ЛЗ є сучасними і мають суттєві переваги при застосуванні в клінічній практиці у порівнянні з доступними аналогами.

ОЦЕНКА ЭКОНОМИЧЕСКОЙ ДОСТУПНОСТИ АНТИГИПЕРТЕНЗИВНОЙ ТЕРАПИИ ГИПЕРТОНИЧЕСКОЙ БОЛЕЗНИ

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Ключевые слова: гипертоническая болезнь; коэффициент доступности; показатель адекватности платежеспособности; антигипертензивные препараты первой линии применения

Гипертоническая болезнь (ГБ) – распространенное заболевание, основными проявлениями которого является повышение артериального давления (АД). В настоящее время ГБ обнаружена у 30-40% взрослого населения стран мира. Распространенность ГБ в популяции с возрастом увеличивается. Среди лиц 18-29 лет распространенность ГБ составляет 4%; в возрасте 50-59 лет – 44%; среди лиц 60-69 лет – 54%, а в возрасте 70 лет и старше – 65%. Целью данной работы была оценка стоимости и экономической доступности антигипертензивных препаратов. В результате проведенного анализа было установлено, что ассортимент антигипертензивных ЛС первой линии применения насчитывает 35 МНН препаратов, которые представлены 570 ТН. Большую часть рынка – 68,5% составляют ЛС зарубежного производства и лишь 31,1% – отечественные ЛС. Ассортимент антигипертензивных ЛС включает препараты разных поколений: наряду с широко известными представлены новые препараты, имеющие существенные преимущества как по клинической эффективности, так и по безопасности. Анализ экономической доступности показал, что подавляющее большинство препаратов является высокодоступными для украинского потребителя, их общее количество составляет 54,3% (19 МНН) от всех представленных ЛС на фармацевтическом рынке Украины. Доля среднедоступных ЛС составляет 37,1% (13 МНН), что позволяет среднестатистическому жителю Украины принимать ЛС в течение всего курса лечения ГБ, не испытывая значительного влияния на собственный бюджет, и лишь 8,6% (3 МНН) являются малодоступными ЛС. Но малодоступные ЛС являются современными и имеют существенные преимущества при применении в клинической практике по сравнению с доступными аналогами.

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MACROLIDE ANTIBIOTICS: THE ANALYSIS OF SOCIO-ECONOMIC AFFORDABILITY

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Key words: antibiotics; affordability; macrolides; coefficient of the solvency adequacy

The structure of the pharmaceutical market of macrolide antibiotics in Ukraine has been analyzed; the coefficient of the solvency adequacy has been calculated within the period of 2012-2014. The analysis of the range of drugs and their socio-economic affordability was conducted during 2012-2014 according to the data of Morion Pharmstandard Analytical Market Research System. To conduct the analysis of socio-economic affordability of drugs the coefficient of the solvency adequacy (Ca.s) expressed in the proportion of the average wage spent on the purchase of one drug package has been calculated. According to the data for 2015 macrolide antibiotics are presented in sufficient quality at the Ukrainian pharmaceutical market: 132 TNs taking into account their dosage forms. The number of foreign drugs exceeds domestic supply: 82 and 50 TNs, respectively. The analysis of the pharmaceutical market for 2012-2015 has shown a downward tendency in the total number of offers for macrolides: from 172 TNs in 2012 to 132 TNs in 2015. However, as this study shows, this reduction is solely due to foreign drugs. The number of domestic offers is unchanged over time. Macrolide antibiotics are presented in a wide range, as well as in a various price range, and their high affordability allows patients to choose the drug taking into account its economic opportunities.

At present, the antimicrobial therapy of various infectious diseases is greatly worsened by development of pathogen resistance. This situation can be seen as a threat to the national security and cause great social and economic harm.

Microorganisms cause infectious diseases since the dawn of humanity and continue this process despite the scientific and practical progress in their treatment achieved in most countries of the world. In recent decades the resistance of pathogens to antimicrobial agents has become a serious problem worldwide [3, 6].

Macrolides have been widely used in clinical practice for more than half a century and proven themselves as highly effective and one of the safest antibiotics.

Increase in interest to macrolide antibiotics in the 1990s was associated mainly with three important trends that appeared at that time [5]. Firstly, within those years there were numerous studies showing that in several European countries, such as France, Spain and Italy, the resistance of pneumococcus, a major causative agent of respiratory disease, to penicillin increased significantly, and reached 40% or more of all strains [2, 3]. At the same time, such a significant change in resistance to macrolides was not reported. And by their clinical efficacy for infectious diseases of the respiratory tract new macrolides did not yield to ampicillin, amoxicillin and oral cephalosporins of the second generation. Secondly, a significant breakthrough in the diagnosis of infections caused by such intracellular pathogens as Chlamydia, Mycoplasma and Legionella, at the end of the 1980s – the beginning of the 1990s, as well as the high antibacterial activity of macrolides against them substantially increased the interest in these drugs. Thirdly, there was quite a lot of works showing that macrolides had the mucoregulatory action, a moderate steroid-like effect, as well as the anti-inflammatory and immunoregulatory effect [2, 4].

Under conditions of the limited health resources and increase in the population needs in providing quality health care the price characteristics of drugs are of great socio-economic value in addition to efficiency and safety indicators. This is due to their direct influence on formation of such an important indicator as affordability of drugs.

The aim of the study was to investigate the range of macrolide antibiotics at the Ukrainian pharmaceutical market and calculate the coefficient of the solvency adequacy in the period of 2012-2014.

Materials and Methods

The analysis of the range of drugs and their socio-economic affordability was conducted during 2012-2014 according to the data of Morion Pharmstandard Analytical Market Research System [1].

To conduct the analysis of socio-economic affordability of drugs the coefficient of the solvency adequacy (Ca.s) expressed in the proportion of the average wage spent on the purchase of one drug package was calculated. Calculations were performed using the formula:

$$Ca.s. = P/Wa.w. \times 100\%,$$

where: Ca.s. – is the coefficient of the solvency adequacy;
P – is the average retail price of one drug package per year;
Wa.w. – is the average wage per year.

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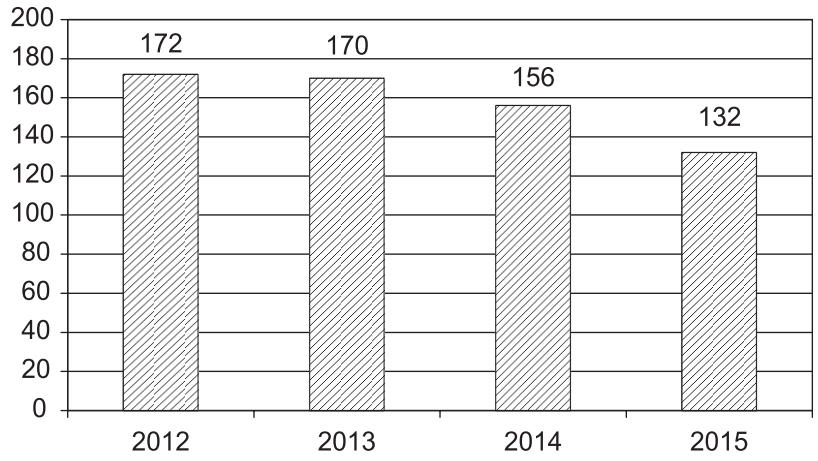

Fig. 1. The number of TNs of macrolides for 2012-1015

To assess affordability the following scale was used: Ca.s ≤ 5% – highly affordable; Ca.s > 5% < 15% – of average affordability; Ca.s ≥ 15% – of low affordability.

The level of the average wage was taken according to the data of the State Statistics Service of Ukraine (www.ukrstat.gov.ua).

Results and Discussion

In 2015, 132 TNs (including dosage forms) of macrolides on the basis of 7 INNs were registered in Ukraine, and among them 38% – domestic ones and 62% – foreign ones.

In the analysis of the data of the pharmaceutical market of macrolide antibiotics in the period from 2012 to 2015 there was a downward tendency in the number of both foreign and domestic drugs: from 172 TNs in 2012 to 132 TNs in 2015. The results are shown in Fig. 1.

During the period studied there was decrease in foreign TNs (from 123 TNs in 2012 to 82 in 2015). The number of domestic TNs is virtually unchanged over time (Fig. 2).

In 2015 the market of macrolides was presented by 74 manufacturers, among which there were 62 foreign and 12 domestic companies. The leaders among the manufacturers by the number of macrolides produced are Teva (Israel), Sandoz (Switzerland), Zdorovye Group of Companies (Ukraine, Kharkiv).

The price range for 2015 was from UAH 5.31 to UAH 799.57. The cheapest drug was Erythromycin produced by Sopharma (Bulgaria), enteric-coated tablets, 100 mg, in blister, No.10, and ROXID 150, Alembic Ltd. (India), film-coated tablets, 150 mg, No.100 was the most expensive.

The next stage of our research was to analyze the socio-economic affordability of macrolide antibiotics at the Ukrainian pharmaceutical market for 2014. To conduct the analysis the standard course of the antibiotic therapy using a daily dose of the drug (depending on the active substance) and the 10-days course of treatment were calculated for each drug. The data are given in Table.

According to the data by Ca.s min obtained the group of drugs with low affordability included drugs on the basis of Josamycin, the group of drugs with average affordability – on the basis of Spiramycin, and the group of highly affordable drugs included drugs on the basis of Erythromycin, Midecamycin, Roxithromycin, Clarithromycin and Azithromycin.

By Ca.s max drugs with low affordability were Spiramycin, Midecamycin, Josamycin, Clarithromycin and Azithromycin. The drugs

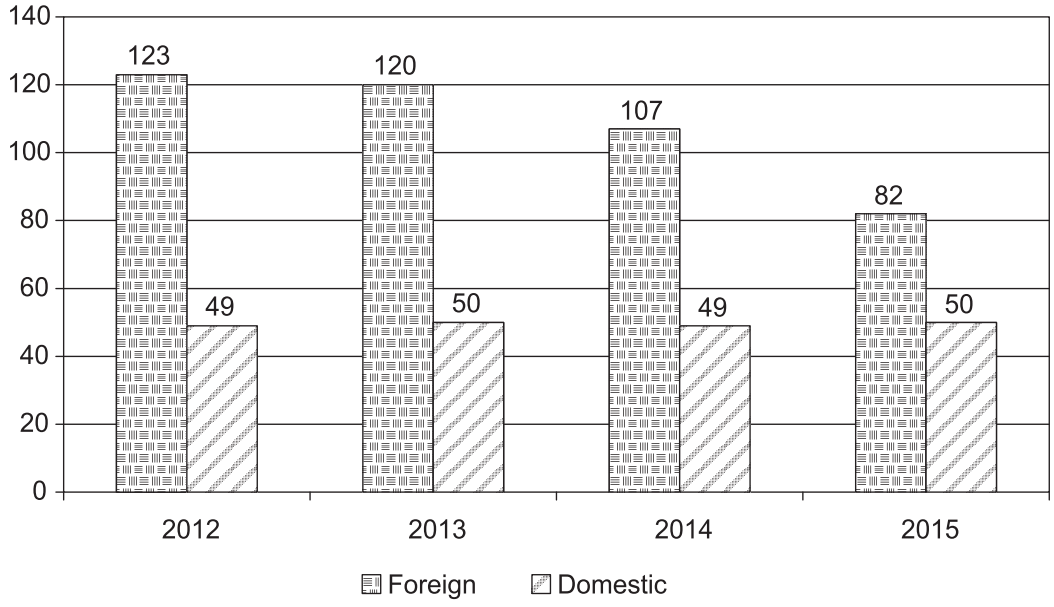

Fig. 2. The proportion of foreign and domestic TNs for 2012-2015

Table

Analysis of the affordability ratio of macrolide antibiotics

INN	min cost per package, UAH	max cost per package, UAH	Ca.s. min, %	Ca.s. max, %
Erythromycin	4.59	21.45	1.25	5.96
Spiramycin	87.36	161.46	13.22	83.20
Midecamycin	49.12	50.31	2.92	15.97
Roxithromycin	17.59	433.96	2.76	3.35
Josamycin	282.75	282.75	17.95	17.95
Clarithromycin	19.58	351.62	1.51	71.04
Azithromycin	4.25	508.71	0.45	64.03

on the basis of Erythromycin were included in the group of drugs with average affordability, and only drugs on the basis of Roxithromycin remained in the group of highly affordable drugs.

The study has shown that at the Ukrainian pharmaceutical market most macrolide antibiotics are highly affordable for customers, and it creates the opportunity to choose the drug for a patient depending on his/her income.

CONCLUSIONS

1. According to the data for 2015 macrolide antibiotics are presented in sufficient quality at the Ukrainian pharmaceutical market: 132 TNs taking into account their dosage forms. The number of foreign drugs exceeds domestic supply: 82 and 50 TNs, respectively.

2. The analysis of the pharmaceutical market for 2012-2015 has shown a downward tendency in the total number of offers for macrolides: from 172 TNs in 2012 to 132 TNs in 2015. However, as this study shows, this reduction is solely due to foreign drugs. The number of domestic offers is unchanged over time.

3. Macrolide antibiotics are presented in a wide range, as well as in a various price range, and their high affordability allows patients to choose the drug taking into account its economic opportunities.

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АНТИБАКТЕРІАЛЬНІ ПРЕПАРАТИ ГРУПИ МАКРОЛІДІВ: АНАЛІЗ СОЦІАЛЬНО-ЕКОНОМІЧНОЇ ДОСТУПНОСТІ

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Ключові слова: антибактеріальні препарати; доступність; макроліди; показник адекватності платоспроможності

Проаналізована структура фармацевтичного ринку антибіотиків групи макролідів в Україні та розрахований показник адекватності платоспроможності в динаміці за 2012-2014 рр. Аналіз асортименту лікарських засобів і їх соціально-економічної доступності проводився за даними аналітичної системи дослідження ринку «Фармстандарт» компанії Моріон за 2012-2014 рр. Для аналізу соціально-економічної доступності ЛЗ розраховували показник адекватності платоспроможності (Ca.s.), який виражається в частці середньої заробітної плати, що витрачається на придбання однієї упаковки ЛЗ. Антибіотики групи макролідів на фармацевтичному ринку України за даними 2015 р. представлені в достатній кількості: 132 ТН з урахуванням ЛФ. Кількість препаратів імпортного виробництва перевищує вітчизняні пропозиції: 82 і 50 ТН відповідно. Аналіз фармацевтичного ринку за 2012-2015 роки показав тенденцію до зниження загальної кількості пропозицій макролідів: з 172 ТН у 2012 році до 132 ТН у 2015 році. Однак як показало дане дослідження, це зниження відбувається виключно за рахунок імпортних препаратів. Кількість вітчизняних пропозицій незмінна з плином часу. Антибіотики групи макролідів представлені в широкому асортименті і в різному ціновому діапазоні, а висока доступність дозволяє пацієнтам вибрати препарат з урахуванням їх економічних можливостей.

АНТИБАКТЕРИАЛЬНЫЕ ПРЕПАРАТЫ ГРУППЫ МАКРОЛИДОВ: АНАЛИЗ СОЦИАЛЬНО-ЭКОНОМИЧЕСКОЙ ДОСТУПНОСТИ

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Ключевые слова: антибактериальные препараты; доступность; макролиды; показатель адекватности платежеспособности

Проанализирована структура фармацевтического рынка антибиотиков группы макролидов в Украине, рассчитан показатель адекватности платежеспособности в динамике за 2012-2014 гг. Анализ ассортимента лекарственных средств и их социально-экономической доступности проводился в течение 2012-2014 годов по данным аналитической системы исследования рынка «Фармстандарт» компании Морион. Для анализа социально-экономической доступности лекарственных препаратов рассчитывали показатель адекватности платежеспособности (Ca.s.), который выражается в доле средней заработной платы, расходуемой на приобретение одной упаковки ЛС. Антибиотики группы макролидов на фармацевтическом рынке Украины по данным 2015 г. представлены в достаточном количестве: 132 ТН с учетом ЛФ. Количество препаратов импортного производства превышает отечественные предложения: 82 и 50 ТН соответственно. Анализ фармацевтического рынка за 2012-2015 годы показал тенденцию к снижению общего количества предложений макролидов: со 172 ТН в 2012 году до 132 ТН в 2015 году. Однако как показало данное исследование, это снижение происходит исключительно за счет импортных препаратов. Количество отечественных предложений неизменно с течением времени. Антибиотики группы макролидов представлены в широком ассортименте и в различном ценовом диапазоне, а высокая доступность позволяет пациентам выбрать препарат с учетом их экономических возможностей.

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