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CLINICAL AND ECONOMIC ANALYSIS PHARMACOTHERAPY OF PATIENTS WITH LIVER CIRRHOSIS IN KHARKIV HOSPITAL

An increased incidence of liver cirrhosis (LC) and the difficult economic situation in Ukraine calls for rational use of financial resources for the treatment of this disease. Objectively assess the cost of medicines (drugs) allows a comprehensive analysis using ABC/VEN/frequency methods carried out in the hospital in Kharkiv according to medical history of 53 patients with LC. According to the study found that the dominant part of the cost used for vital drugs, which are often prescribed to patients with LC. However, LC pharmacotherapy in a health care facility did not always comply with the regulations, because from 3.56% to 18.75% costs was spent on drugs missing from the clinical protocols for LC treatment and comorbidities as well as from the National Drug Formulary of Ukraine. Therefore, it is possible to optimize costs by reducing prescriptions of minor drugs and administering those drugs that are included in the clinical protocol of LC treatment.

Key words: drugs for the treatment of liver cirrhosis; clinical and economic analysis; National Drug Formulary of Ukraine, clinical protocols for LC treatment.

STATEMENT OF THE PROBLEM

Significant place in the structure of digestive diseases liver cirrhosis (LC), remaining relevant socio-economic and clinical and epidemiological health problem all over the world. This is due to the prevalence major etiological factors in the form of dissemination hepatotropic viruses, combined with increasing alcohol consumption, and high mortality. According to WHO for the past 20 years, the mortality rate of LC increased to 10-20 per 100 thousand population per year. Today mortality LC in the world ranks 10th [5].

ANALYSIS OF RECENT RESEARCH AND PUBLICATIONS

Ukraine also increases the incidence of LC, and 79.6% of patients are most active working age - 30-50 years [6]. This situation necessitates the optimization of treatment of patients with LC in health care facilities (HCF) through clinical and economic analysis to assess the compliance of LC pharmacotherapy with the regulatory requirements of the Ministry of Health of Ukraine.

HIGHLIGHTING THE UNSOLVED PARTS OF THE GENERAL PROBLEM

One of the problems associated with LC - lack of timely diagnosis and effective treatment, leading to high mortality from this disease. Statistical data do not always correspond to the prevalence of LC, and treatment - recommended clinical protocol. In the absence of periodicals Ukraine, the current issues are of clinical and economic evaluation of treatment outcomes LC in health care facilities in Ukraine.

The objective of this study is a comprehensive assessment of consumption of medicines (drugs) and determining the degree of rationality of real pharmacotherapy of patients with LC who were treated in HCF of Kharkiv during 2013 by analyzing its regulatory compliance with: 5th edition of the National Drug Formulary of Ukraine and clinical protocol of LC treatment based on the results of the integrated ABC/VEN/frequency analysis [3].

SUMMARY OF THE MAIN RESEARCH MATERIAL RESEARCH METHODS

To achieve this goal it is necessary to perform the following tasks: to conduct a retrospective analysis of treatment sheets of patients with LC; determine the frequency of prescription of drugs

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to patients with LC; based on the results of formal VEN-analysis, evaluate compliance of LC therapy with the regulatory requirements of the Ministry of Health of Ukraine: according to the presence of drugs in the National Drug Formulary of Ukraine (5th edition, 2013) and treatment protocols of LC and comorbidities (Order of the Ministry of Health of Ukraine No 271 dated 13.06.2005 "On approval of protocols of health care on the specialty "Gastroenterology"); determine the structure and rationality of costs of LC therapy based on the results of the ABC-analysis [3].

A retrospective clinical and economic analysis was based on data from treatment sheets of patients with LC who were treated in the gastroenterology department of a hospital in Kharkov during 12 months in 2013. To conduct an analysis, a sample of 53 patients with primary diagnosis – "liver cirrhosis" – was formed. Male patients were the larger part of patients – 30 patients, and female patients were the smaller part – 23 patients, respectively. The age of patients ranged from 32 to 68 years. The average term of patient's staying in the in-patient department was 14 ± 1.8 days, which generally non correspond to the clinical protocol of health care for patients with LC (Order of the Ministry of Health of Ukraine No 271 dated 13.06.2005), according to which treatment should last 1 month inpatient, and prolonged symptomatic treatment in an outpatient setting. To determine the cost of a course of treatment with drugs that were administered to patients with LC, the average weighted price in the study period in pharmacies of Ukraine was used [4].

RESULTS AND DISCUSSION

The analysis of case histories of showed that the occurrence of LC etiology in 22 patients had viral etiology in 21 patients - toxic genesis and LC 10 patients had mixed etiology. Pharmacotherapy patients mostly consistent clinical protocols of care for patients with LC (Order of the Ministry of Health of Ukraine No 271 dated 13.06.2005). Treatment of patients with LC included diet (table number 5), pathogenetic therapy (antibiotics) causal treatment (antivirals), metabolic, coenzyme, vitamin, detoxification and diuretic therapy, and when complications - treatment of portal hypertension and liver en tsefalopatiyi. The disadvantage of pharmacotherapy in this department of a hospital was that among 22 patients with LC viral etiology only 5 patients were assigned antiviral agents. Each patient in LC were detected between 2 and 6 comorbidities, including frequent: pancreatitis (24 patients), cholecystitis (25 patients), secondary hypochromic anemia (15 patients), hastroudenit

(11 patients). All patients were identified certain difficulties, including frequent: portal hypertension (39 patients), hepatic encephalopathy (20 patients), ascites (12 patients). Satisfactory condition at discharge was 51% of patients, and unstable state (requires re-hospitalization) - 49%, which may indicate that insufficient care.

The analysis showed that patients were administered the total of 110 drugs by trade names (TNs), from 34 pharmacotherapeutic groups. The number of prescriptions for 1 patient averaged 8 drugs and indicates the presence of polypharmacy, recommended as the optimal number of drugs in 1 patient must not exceed 4-5 drugs. The first place for the number of designated group took drugs hepatotropic (15 TNs). The cost of treatment of 53 patients with LC over the study period amounted to 100,594.88 UAH. On average, 1,898.00 UAH were spent on a course of treatment per patient.

The next stage of our study was to estimate costs rationality based on the results of the ABC analysis that included the distribution of drugs into three groups according to costs. The results of the ABC analysis showed that the group "A" included 20 drugs, the cost of which amounted to 79.62% of all funds. The group "B" included 33 drugs, the cost of which amounted to 15.01% and the group "C" included 62 drugs, the cost of which amounted to 5.3% of the total costs.

The next stage of our study was to estimate costs rationality based on the results of the ABC analysis that included the distribution of drugs into three groups according to costs. The results of the ABC analysis showed that the group "A" included 20 drugs, the cost of which amounted to 79.62 %, and the absolute value 80,095.94 UAH. The group "B" included 30 drugs, the cost of which amounted to 15.53% (15,624.45 UAH). The group "C" included 60 drugs, the cost of which amounted to 4.85% (4,873.49 UAH).

Drugs in the group "A" are the priority and of the most interest in the analysis of the results (Table). In Table. 1 shows the distribution of costs (as a percentage of total expenditure) in group A drugs for TN. Up to 10 more costly drugs A group of drugs includes pathogenetic and symptomatic therapy securities, which spent 65% of costs: hepatoprotectors Heptral, Phosphogliv, Ornitox, Glutargin, Hepadif, Urschol, enzyme means Espalipon and Nolpaza, drug detoxification Reamberin and amino acids Tivortyn. Hence, most of the funds spent on drugs for the treatment of LC.

To determine the rationality of costs money on treatment LC, an essential element of the study was VEN-analysis, ie conformity assessment pharmacotherapy of the regulatory requirements

Table

COMPARISON OF FREQUENCY AND VEN ANALYSIS WITH DRUGS IN GROUP A

| No | TN of the drug | Pharmaceutical form | Average weighted price of package, UAH | Frequency of prescriptions | Cost of a course of treatment of patients, UAH | % of the cost | ABC rank | National Drug Formulary | Clinical protocols of TH and comorbidities |
|----|--------------------|-------------------------------------|--|----------------------------|--|---------------|----------|-------------------------|--|
| 1 | Heptral | solution for injection 5 ml, No 5 | 680.29 | 17 | 20,053.54 | 19.93 | A | V | V/N |
| 2 | Phosphogliv | solution for injection 2.5 g, No 5 | 197.31 | 21 | 13,325.53 | 13.25 | A | N | V/N |
| 3 | Ornitox | solution for injection 10 ml, No 5 | 369.21 | 8 | 6,007.76 | 5.97 | A | V | V/N |
| 4 | Reamberin | solution for infusion 200 ml | 57.26 | 17 | 5,548.49 | 5.52 | A | V | V/N |
| 5 | Nolpaza | solution for injection 40 mg No 1 | 94.98 | 4 | 4,938.96 | 4.91 | A | V | V/N |
| 6 | Tivortyn | solution for infusion 100 ml | 103.36 | 3 | 3,618.63 | 3.6 | A | V | V/N |
| 7 | Glutargin | solution for injection 5 ml No 10 | 247.95 | 6 | 3,612.14 | 3.59 | A | V | V/N |
| 8 | Espa-lipon | solution for injection 600 mg No 5 | 310.09 | 5 | 2,945.86 | 2.93 | A | V | V/N |
| 9 | Hepadif | capsules No 50 | 563.70 | 7 | 2,569.56 | 2.55 | A | N | V/N |
| 10 | Ursohol | capsules 250 mg No 50 | 254.94 | 18 | 2,492.70 | 2.48 | A | V | V/N |
| 11 | Veroshpiron | capsules 100 mg No 30 | 151.63 | 39 | 2,410.98 | 2.4 | A | V | V/N |
| 12 | Essentiale H | solution for injection 5 ml No 5 | 140.10 | 6 | 2,185.56 | 2.17 | A | V | V/N |
| 13 | Thyotriazolium | solution for injection 2 ml, No 10 | 73.24 | 21 | 2,153.26 | 2.14 | A | V | V/N |
| 14 | Heptral | tablets 400 mg, No 20 | 707.73 | 2 | 1,627.78 | 1.62 | A | V | V/N |
| 15 | Gepasol Neo 8% | solution for injection 500 ml No 1 | 135.95 | 4 | 1,413.88 | 1.41 | A | V | V/N |
| 16 | Dufalak | syrup 500 ml | 189.69 | 7 | 1,168.76 | 1.16 | A | V | V/N |
| 17 | Thyotriazolium | solution for injection 4 ml No 10 | 121.09 | 8 | 1,076.25 | 1.07 | A | V | V/N |
| 18 | Aminosteryl H hepa | solution for injection 500 ml No 10 | 2513.24 | 2 | 1,005.30 | 1.00 | A | V | V/N |
| 19 | Neyrobion | solution for injection 3 ml No 3 | 57.65 | 12 | 991.58 | 0.99 | A | N | N/N |
| 20 | Kontrikal | tablets 40 mg, No 14 | 474.71 | 1 | 949.42 | 0.94 | A | N | N/N |

of Ukraine. As a result of formal VEN-analysis it has been found that from all drugs 13 drugs (12%) were not included in the National Drug Formulary (5th edition), we're not included in the treatment protocols of LC and comorbidities 11 drugs (10%). Cost analysis was performed on those drugs are not included in the regulations. It was established that drugs are not included in the National Drug Formulary of Ukraine spent 18.75 % of the total costs, and the drugs that are not included in the clinical treatment protocols LC and comorbidities spent 3.56 % of total costs for pharmacotherapy. Thus, despite the fact that vitally necessary medicines are a significantly greater proportion in prescriptions of pharmacotherapy of patients with LC, it is necessary to conduct a further search for ways to reduce the cost of minor drugs for increase in the compliance of LC treatment with the regulatory requirements.

Comparison of results of ABC/frequency analysis showed that all of the most used drugs were in group A (Table 1). Comparison of frequency/VEN-analysis showed that the most prescribed drugs: Veroshpiron, Inderal, Fosfohliv, Thiotriazolin and Urschol included in the clinical treatment protocol LC. Only hepatotropic drug Phosphogliv, produced by Pharmstandard (Russia), was not included in the National Drug Formulary (5th edition), indicating its insufficient evidence base.

Summarizing the findings, we can conclude that doctors preferred drugs recommended by the applicable national standards of the Ministry of Health of Ukraine to treat both LC and comorbidities.

CONCLUSIONS AND PROSPECTS FOR FURTHER RESEARCH

1. According to the results of the clinical and economic analysis, LC pharmacotherapy gener-

ally complied with the clinical treatment protocol, but the average number of prescriptions 8 drugs per patient showed polypharmacy. The average duration of treatment of a patient in the hospital for 14 days did not corresponded to a desired period of time (30 days), according to the clinical protocol treatment of LC.

2. The integrated ABC/VEN/frequency analysis demonstrated the need for correction of LC pharmacotherapy as much of the funds from 3.56 to 18.75 % was spent on drugs missing from the clinical protocols for treatment of LC and comorbidities as well as from the National Drug Formulary of Ukraine.

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УДК 615.244: 615.036:615.11**О. В. Ткачова****КЛІНІКО-ЕКОНОМІЧНИЙ АНАЛІЗ ФАРМАКОТЕРАПІЇ
ХВОРИХ НА ЦИРОЗ ПЕЧІНКИ У ЛІКАРНІ МІСТА ХАРКОВА**

Ріст захворюваності на цироз печінки (ЦП) та складна економічна ситуація в Україні обумовлює необхідність раціонального використання грошових ресурсів на лікування цього захворювання. Об'єктивно оцінити витрати на лікарські засоби (ЛЗ) дозволяє комплексний аналіз з використанням АВС/VEN/частотного методів, що було проведено у лікарні м. Харкова за даними історій хвороб 53 хворих на ЦП. За результатами дослідження встановлено, що домінуюча частина коштів витрачена на життєво необхідні ЛЗ, що частіше призначались хворим на ЦП. Проте фармакотерапія ЦП не завжди відповідає нормативним документам, оскільки від 3,56 до 18,75 % всіх коштів було витрачено на ЛЗ, що відсутні в клінічних протоколах лікування ЦП та супутніх захворювань і в Державному формулярі ЛЗ України. Тому, можливим є оптимізація витрат шляхом зменшення призначень другорядних ЛЗ для лікування ЦП.

Ключові слова: ЛЗ для лікування цирозу печінки, клініко-економічний аналіз, Державний формуляр ЛЗ України, клінічний протокол лікування ЦП.

УДК 615.244: 615.036:615.11**О. В. Ткачова****КЛИНИКО-ЭКОНОМИЧЕСКИЙ АНАЛИЗ ФАРМАКОТЕРАПИИ
БОЛЬНЫХ ЦИРРОЗОМ ПЕЧЕНИ В БОЛЬНИЦЕ ГОРОДА ХАРЬКОВА**

Рост заболеваемости циррозом печени (ЦП) и сложная экономическая ситуация в Украине обуславливают необходимость рационального использования денежных ресурсов на лечение этого заболевания. Объективно оценить затраты на лекарственные средства (ЛС) позволяет комплексный анализ с использованием АВС/VEN/частотного метода, который был проведен в больнице г. Харькова по данным историй болезней 53 больных ЦП. По результатам исследования установлено, что доминирующая часть средств потрачена на жизненно необходимые ЛС, что чаще назначались больным ЦП. Однако фармакотерапия ЦП не всегда соответствовала нормативным документам, поскольку от 3,56 до 18,75 % всех средств было потрачено на ЛС, отсутствуют в клинических протоколах лечения ЦП и сопутствующих заболеваний и в Государственном формуляре ЛС Украины. Поэтому, возможным является оптимизация расходов путем уменьшения назначений второстепенных ЛС для лечения ЦП.

Ключевые слова: ЛС для лечения цирроза печени, клинико-экономический анализ, Государственный формуляр ЛС Украины, клинический протокол лечения ЦП.

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