Журнал «Перспективи та інновації науки»
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ANALYSIS OF THE EFFECTIVENESS OF TREATMENT SCHEMES FOR DISEASES WITH BRONCHO-OBSTRUCTIVE SYNDROME IN PATIENTS OF MNCE "HAYSYNSKA CDH OF HCC"

Abstract. Diseases accompanied by broncho-obstructive syndrome, in particular bronchial asthma (BA) and chronic obstructive pulmonary disease (COPD), are significant factors that affect the quality of life and functionality of patients. The effectiveness of the therapy of these pathologies depends on the optimal selection of drugs, the adequacy of dosage and the possibility of reducing the financial burden for both patients and the health care system. Modern pharmacoepidemiology provides opportunities for evaluating the effectiveness and economic feasibility of treatment regimens, which allows determining optimal approaches to therapy. However, there is insufficient data on the effectiveness of various treatment regimens for asthma and COPD in local medical institutions, which limits the possibilities of adapting international protocols to the conditions of real clinical practice. The purpose of this study was to conduct a comparative analysis of the effectiveness and cost-effectiveness of three regimens for the treatment of broncho-obstructive diseases in patients of the MNCE "Haysynska CDH of HCC". The study included schemes based on the drugs Symbicort Turbuhaler (formoterol + budesonide), Seretide Diskus (salmeterol + fluticasone) and Beklazon-Eko (beclomethasone). Efficacy assessment included analysis of technical efficiency according to the Farrell index and cost-effectiveness for each regimen, taking into account dosage, resource costs and the influence of co-factors such as age, sex, and year of follow-up. The study showed that of the three schemes for the treatment of bronchial asthma (BA) and chronic obstructive pulmonary disease (COPD), the third scheme (Beklazon-Eko, 8 patients) turned out to be the most technically effective, although its limited sample affects the generalizability of the results. Only 4 patients out of 154 achieved optimal performance indicators, which indicates the need to adapt doses to the individual needs of patients.

Журнал «Перспективи та інновації науки»
(Серія «Педагогіка», Серія «Психологія», Серія «Медицина»)
№ 11(45) 2024

Overdosage was observed in 103 patients. Treatment efficacy among patients with AD was higher than among patients with COPD, with only 6 of 107 patients with COPD achieving optimal prescribed doses, compared with 8 of 47 patients with AD. The first scheme (Symbicort Turbuhaler) had consistently higher efficiency index values at all centiles of the distribution, which ensured its superiority over the second scheme (Seretide Discus), which had a significantly lower cost-effectiveness (p = 4.281e-11). Cost-effectiveness was affected by the year of observation: it increased for the first scheme, while it decreased for the second from 2019 to 2024. Thus, in conclusion, the most effective in terms of costs and technical efficiency is the third treatment regimen, although its benefits are limited to a small sample of patients. The first regimen demonstrates more sustained efficacy among patients, while the second regimen has lower cost-effectiveness and technical effectiveness.

Keywords: chronic obstructive pulmonary disease, bronchial asthma, treatment regimens, treatment effectiveness, cost-effectiveness.

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АНАЛІЗ ЕФЕКТИВНОСТІ СХЕМ ЛІКУВАННЯ ЗАХВОРЮВАНЬ З БРОНХООБСТРУКТИВНИМ СИНДРОМОМ У ПАЦІЄНТІВ КНП «ГАЙСИНСЬКОЇ ЦРЛ ГМР»

Анотація. Захворювання, що супроводжуються бронхообструктивним синдромом, зокрема бронхіальна астма (БА) та хронічне обструктивне захворювання легень (ХОЗЛ), є значущими факторами, які впливають на якість життя та функціональність пацієнтів. Ефективність терапії цих патологій залежить від оптимального підбору препаратів, адекватності дозування та можливості зниження фінансового тягаря як для пацієнтів, так і для системи охорони здоров’я. Сучасна фармакоепідеміологія надає можливості для оцінки ефективності та економічної доцільності схем лікування, що дозволяє визначити оптимальні підходи до терапії. Однак недостатньо даних щодо ефективності різних схем лікування БА та ХОЗЛ у місцевих лікувальних установах, що обмежує можливості адаптації міжнародних протоколів до умов реальної клінічної практики. Метою цього дослідження було провести порівняльний аналіз ефективності та витрати-ефективності трьох схем лікування

Журнал «Перспективи та інновації науки»
(Серія «Педагогіка», Серія «Психологія», Серія «Медицина»)
№ 11(45) 2024

бронхообструктивних захворювань у пацієнтів КНП «Гайсинської ЦРЛ ГМР». Дослідження охоплювало схеми, що базуються на препаратах Симбікорт Турбухалер (формотерол + будесонід), Серетид Дискус (сальметерол + флутиказон) та Беклазон-Еко (беклометазон). Оцінка ефективності включала аналіз технічної ефективності за індексом Фаррела та витрати-ефективності для кожної схеми з урахуванням дозування, витрат ресурсів і впливу супутніх факторів, таких як вік, стать, та рік спостереження. Дослідження показало, що з трьох схем лікування бронхіальної астми (БА) та хронічного обструктивного захворювання легень (ХОЗЛ) найбільш технічно ефективною виявилася третя схема (Беклазон-Еко, 8 пацієнтів), хоча її обмежена вибірка впливає на узагальненість результатів. Лише 4 пацієнти з 154 досягли оптимальних показників ефективності, що свідчить про потребу в адаптації доз до індивідуальних потреб пацієнтів. У 103 пацієнтів спостерігалося надмірне дозування. Ефективність лікування серед пацієнтів із БА була вищою, ніж у пацієнтів із ХОЗЛ: лише 6 із 107 пацієнтів з ХОЗЛ досягли оптимальних доз призначень, порівняно з 8 із 47 пацієнтів з БА. Перша схема (Симбікорт Турбухалер) мала стабільно вищі значення індексу ефективності на всіх центилях розподілу, що забезпечило її перевагу перед другою схемою (Серетид Дискус), яка мала достовірно нижчу витрати-ефективність ($p = 4.281e-11$). На витрати-ефективність впливав рік спостереження: для першої схеми вона підвищилась, тоді як для другої знизилась з 2019 до 2024 року. Таким чином, у підсумку, найбільш ефективною з точки зору витрат та технічної ефективності є третя схема лікування, хоч її переваги обмежені малою вибіркою пацієнтів. Перша схема демонструє більш стійку ефективність серед пацієнтів, тоді як друга схема має нижчі показники витрат-ефективності та технічної ефективності.

Ключові слова: хронічне обструктивне захворювання легень, бронхіальна астма, схеми лікування, ефективність лікування, витрати-ефективність.

Statement of the problem. Diseases with broncho-obstructive syndrome include a number of nosologies. Of which, bronchial asthma and chronic obstructive pulmonary disease are the most common and a problem for both patients and medical professionals [1]. Asthma, together with COPD, are among the most common pathologies of the human respiratory system. Thus, from 1990 to 2000, the prevalence of asthma in the world increased from 4.1 to 6.6% [2] and as of 2017, the total number of asthma patients in the world is about 272.7 million with the prevalence of asthma among women at the level of 3 .6%, and among men at the level of 3.3% [3]. In Ukraine, the prevalence of asthma among the adult population of Ukraine is 0.5% [4]. The prevalence of COPD is about 9.23% in men and 6.16% in women [5], and a total of about 227.3 million people suffer from this pathology in the world [6].

In this regard, modern medicine is interested not only in creating new drugs for the treatment of these pathologies, but also in evaluating the effectiveness of

therapy of already existing drugs. Modern therapy of such pathologies includes bronchodilators and corticosteroids, which shorten the duration of an exacerbation by 3-4 days and reduce the risk of recurrence by 30% [7]. According to the latest Global Initiative for Asthma (GINA) 2024 guidelines, the mainstay of treatment is inhaled corticosteroids (ICS) in combination with bronchodilators, which significantly reduces the frequency of exacerbations and improves symptom control. The use of ICS reduces the risk of exacerbation by 30-40%, and symptom control improves in 70% of patients [8].

At the same time, the effectiveness of using pharmacological regimens against bronchial asthma and COPD is poorly studied in Ukraine, especially in district hospitals, which requires careful analysis.

Connection of the publication with planned scientific research works. The work was carried out as part of the research work of the National Pirogov Memorial Medical University, Vinnytsya: “Effectiveness and safety of chemotherapeutic agents and metabolic correctors in conditions of comorbid pathology” (state registration number 0119U000069).

The purpose of the article – to conduct an analysis of the effectiveness of treatment schemes for diseases with broncho-obstructive syndrome on the example of patients who were treated at the MNCE "Haysynska CDH of HCC".

Research objects and methods. In order to achieve the goal, the recommendations of doctors for outpatient treatment of 154 patients of the therapeutic department of the Communal non-profit enterprise "Haysynska Central District Hospital of the Haysynsk City Council" were analyzed in the period from 2019 to 2024, of which 107 patients had chronic obstructive pulmonary disease, and 47 for bronchial asthma. The recommendations were analyzed according to drug regimens and their cost in US dollars at the moment of the research for 1 month of treatment. We also analyzed the dates of the next exacerbation of the patient data using the MedAir medical information system to obtain data on the cost-effectiveness ratio.

Treatment schemes were analyzed:

1) Symbicort turbohaler (manufactured by AstraZeneca AB, Sweden): Formoterol + Budesonide – 51 patients;

2) Seretide diskus (producer Glaxo Wellcome Production, France): Salmeterol + Fluticasone – 90 patients;

3) Beklazon-Eko (manufacturer Norton (Waterford) Limited, Ireland) – Beclomethasone - 8 patients.

For statistical processing of the obtained results, we used the analytical system R, version 4.3.1 (2023-06-16) GNU GPL license v.(>= 2) svn.rev 84548, using the "aarch64-apple-darwin20" platform, the "Benchmarking" library ", "readxl", "ggplot2", "AER", DEA analysis functions eff(), dea(), cost.opt(), dea.boot(), sdea(), slack(), statistical test functions ks. test(), qf(), tobit regression function tobit().

Efficacy was determined by volume to establish dosing inefficiencies. The optimal doses were determined as the ratio of E indices according to CRS (Constant Returns to Scale) to those according to VRS (Variable Returns to Scale). Optimality

Журнал «Перспективи та інновації науки»
(Серія «Педагогіка», Серія «Психологія», Серія «Медицина»)
№ 11(45) 2024

is achieved by the value of the ratio 1. Insufficient or excessive dosage is determined by comparing the VRS index with that according to DRS (Decreasing Returns to Scale), namely if VRS<DRS, we have insufficient dosage, and when VRS=DRS and the efficiency due to the volume is less than one we determine the excess dosage. and technical efficiency by distance to the frontier.

The study of the effectiveness of the main treatment (basic therapy) of AB and COPD was carried out on the basis of the technical efficiency of product production with constant resources, i.e. output efficiency according to the Farrell index

We also studied both the efficiency of resource use, i.e. input efficiency according to the inverse Farrell index E, and the technical efficiency of product production with unchanged resources, i.e. output efficiency according to the Farrell index (Farrell efficiency, F~1/E). The indicated indices were determined using DEA (Data Envelopment Analysis), namely the resource efficiency index, which is sought by their (x) minimization:

$$E^0 = E((x^0, y^0); T^*) = min\{E \in \Re_+ | (Ex^0, y^0) \in T^*\}$$

and the Farrell index by maximizing the produced product (days to the next exacerbation):

$$F^0 = F((x^0, y^0); T^*) = max\{F \in \Re_+ | (x^0, Fy^0) \in T^*\}$$

We determined the cost-effectiveness index, which has a scale from 0 (zero efficiency) to 1 (100% efficiency). The cost-effectiveness criterion takes into account not only the resources, the produced product, but also the prices of resources, that is, it adds a price component to the consideration, and therefore it is considered preferable. It is calculated as the ratio of optimal costs for a given frontier to those observed for the same manufactured product.

Analysis of factors that significantly modified the cost-effectiveness criterion according to treatment schemes was carried out on the basis of tobit regression ("AER" library of the international analytical system R). The analysis was performed only for the first and second schemes that had a sufficient number of patients. The basic formulation of the model works is presented below, α is the vector of model coefficients presented in the article, ε are the residuals of the model with a standard normal distribution, i.e. ε~N(0,σ^2). The estimate of the scaling parameter σ, or rather the logarithm of the estimate, is presented in the last line as the effect "Log(scale)".

$$E = \begin{cases} 0, & \text{if } az + \varepsilon \le 0 \\ az + \varepsilon & \text{if } 0 < az + \varepsilon < 1 \\ 1 & \text{if } az + \varepsilon \ge 1 \end{cases}$$

Журнал «Перспективи та інновації науки»
(Серія «Педагогіка», Серія «Психологія», Серія «Медицина»)
№ 11(45) 2024

Studies do not contradict the basic bioethical standards of the Declaration of Helsinki, the Council of Europe Convention on Human Rights and Biomedicine (1977), the relevant WHO regulations and laws of Ukraine.

Presentation of the main material.

Research results and their discussion. Resource efficiency analysis: input efficiency analysis showed that only 4 patients out of 154 included in the analysis reached the efficiency frontier, which is evidence that the basic therapy regimens are poorly adapted to patients. Analysis of effectiveness due to volume: it was established that only in 51 of 154 patients the doses turned out to be optimal, while in the vast majority they were excessive. The result showed that all patients with a volume effect less than 1, namely 154-51=103 patients, were overdosed. Study of the effectiveness of the main treatment (basic therapy) of AB and COPD: 8 out of 47 patients with BA formed the frontier of technical efficiency according to the Farrell index, that is, they had optimal appointments. Whereas only 6 out of 107 patients with COPD had optimal appointments. The distribution by centiles is shown in Table 1.

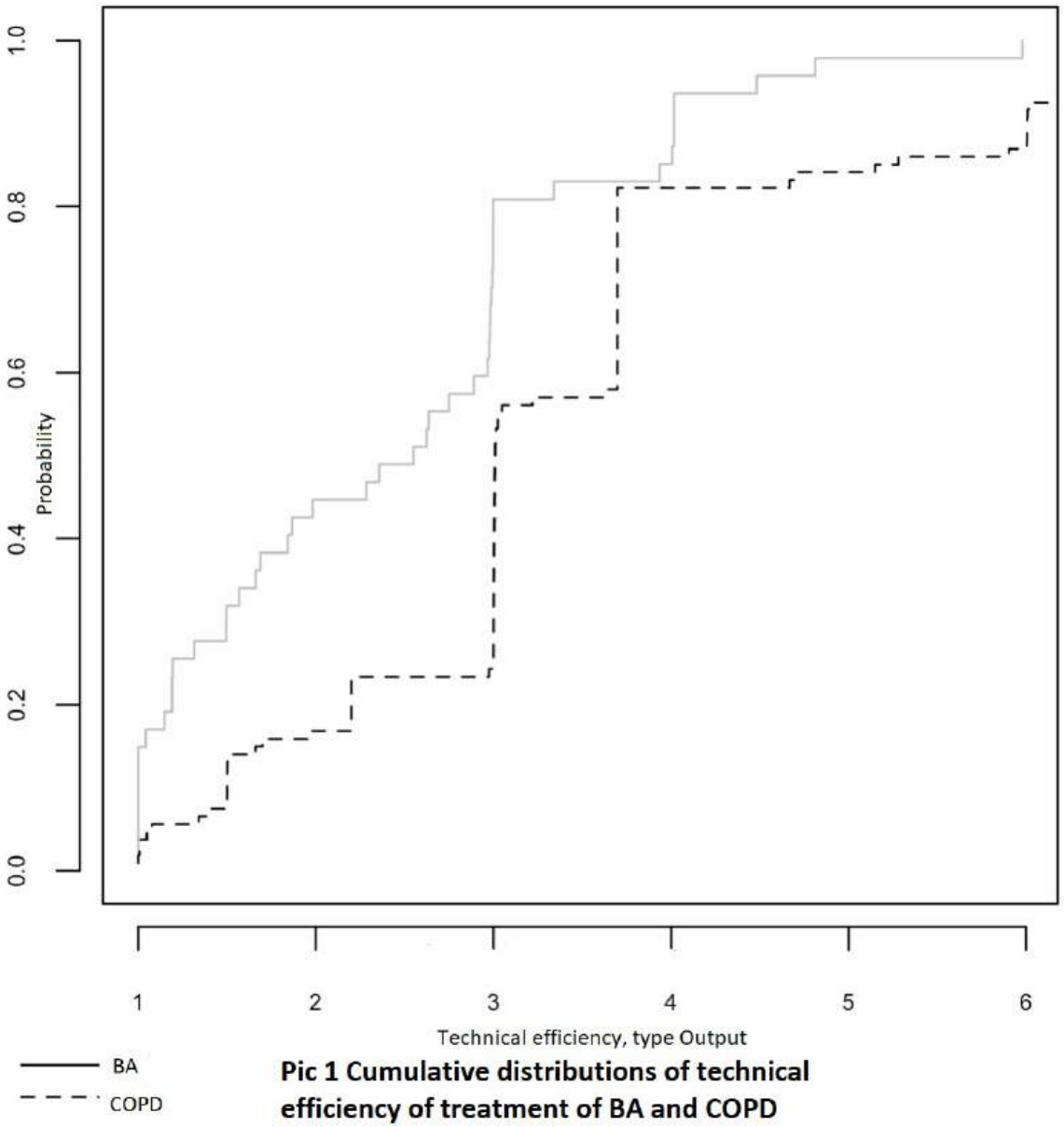
Table 1.

Summarized data of the analysis of the efficiency of resource use, efficiency due to volume and efficiency of the main treatment of patients with broncho-obstructive syndrome in MNCE "Haysynska CDH of HCC".

	Min	25%	50%	Mean	75%	Max
Input E	0.01638	0.1	0.32799	0.28031	0.33265	1
By volume	0.3	0.3007	0.3023	0.5331	1	1
BA Farrell	1	1.255	2.550	2.431	2.998	5.978
COPD Farrell	1	3	3.010	3.675	3.699	12.543
Scheme 1 Farrell	1	1	1.768	1.824	2.537	3.552
Scheme 2 Farrell	1	1.799	2.004	2.182	2.799	4.797
Scheme 3 Farrell	1	1.001	1.182	1.376	1.730	2.005
Scheme 1 CE	0.2822	0.4321	0.5656	0.6490	1	1
Scheme 2 CE	0.05	0.2	0.4962	0.4438	0.4994	1
Scheme 3 CE	0.4976	0.4999	0.8181	0.7666	0.9995	1

Журнал «Перспективи та інновації науки»
(Серія «Педагогіка», Серія «Психологія», Серія «Медицина»)
№ 11(45) 2024

From the data presented in the table, it can be seen that 50% of patients were characterized by an efficiency index lower than 0.328, and in a quarter the index did not exceed 0.1. From these distributions, it is possible to conclude about the better effectiveness of prescriptions for patients with BA. Graphically, the functions of the cumulative distributions of the values of the Farrell index of patients with BA and COPD are shown in Fig. 1.



Pic 1 Cumulative distributions of technical efficiency of treatment of BA and COPD

A rather wide area between the curves indicates large discrepancies, the testing of which was carried out on the basis of both the parametric Fisher test (F) and the non-parametric test of the discrepancy between two cumulative Kolmogorov distributions. The results of the two tests are shown in Table 2.

Журнал «Перспективи та інновації науки»
(Серія «Педагогіка», Серія «Психологія», Серія «Медицина»)
№ 11(45) 2024

Table 2.

Analysis of the effectiveness of prescriptions for patients with broncho-obstructive syndrome at MNCE "Haysynska CDH of HCC".

	Kolmogorov's test	F - test	95% CI
BA - COPD, Farrel	D = 0.56552, p-value = 3.079e-10	0.5349874	0.7002284 - 1.395069
Scheme 1 vs 2, Farrel	D = 0.43856, p-value = 3.31e-06	0.6968139	0.7022636 - 1.400427
Scheme 1 vs 3, Farrel	D = 0.35294, p-value = 0.2333	2.189973	0.5164152 - 2.394595
Scheme 2 vs 3, Farrel	D = 0.56111, p-value = 0.009373	3.142838	0.5325012 - 2.361174
Scheme 1 vs 2, CE	D = 0.58954, p-value = 4.281e-11	0.6309457	0.7022636-1.400427
Scheme 1 vs 3, CE	D = 0.2549, p-value = 0.5874	1.503605	0.5164152-2.394595
Scheme 2 vs 3, CE	D = 0.66389, p-value = 0.00115	2.383097	0.5325012-2.361174

The reliability value of the Kolmogorov test p = 3.079e-10, that is, it indicates the presence of highly reliable differences in the curves, the same is indicated by Fisher's parametric test with a test statistic of 0.5349874, which is outside the 95% confidence interval of the F-distribution, namely 0.7002284 - 1.395069. This suggests that a significantly better effectiveness of basic therapy for patients with BA has been established.

Comparative analysis of the effectiveness of treatment schemes based on basic therapy according to Farrell's criteria. We took into account both basic and accompanying therapy, that is, we considered the treatment in a complex, although the scheme was determined precisely by the main therapy. Three such common schemes were found, with the corresponding number of patients 51, 90, and 8. The technical efficiency of Output was studied according to Farrell's criterion. Given in Table 1, the centiles of distributions of the Farrell index of patients according to three treatment schemes indicate the advantage of the third scheme, however, its advantage is compromised by a small number of observations, so the main conclusions must be presented in the future according to the first and second schemes. In this case, the first scheme prevails, which has smaller values of the Farrell index at all centiles of the distribution, which indicates its regularly higher efficiency. The results of the application of the non-parametric Kolmogorov and parametric F tests are shown in Table 2. There is a significant difference in the

Журнал «Перспективи та інновації науки»
(Серія «Педагогіка», Серія «Психологія», Серія «Медицина»)
№ 11(45) 2024

efficiency between the first and second groups, the p-level of confidence is very high (p=3.31e-06), the Fisher test score of 0.6968139 is outside the 95% confidence interval. Scheme 2 also has significantly lower Farell efficiency compared to scheme No. 3, namely the p-level of the Kolmogorov test corresponds to 0.009373 centile of the criterion distribution density. The reliability of the effectiveness is also evidenced by the estimate of Fisher's test of 3.142838, which is outside the confidence interval. No significant differences in Farrell efficiency were found between the first and third schemes.

Comparative analysis of treatment schemes based on basic therapy according to cost-effectiveness (CE) criteria. This analysis cannot be performed for patients with asthma and COPD, as different schemes are used for each group of nosologies. However, this can be done according to treatment schemes. We also took into account both basic and adjunctive therapy, and the scheme was determined by the main therapy. Accordingly, the schemes included 51, 90, and 8 patients.

As in the case of Farrell's technical efficiency, the cost-effectiveness index favors the third regimen (see Table 1), where 3 of 8 patients had an index value greater than 0.999. Under the first scheme, this number was 17 out of 51, under the second 6 out of 90. The indicated differences are regular across all centiles, that is, they apply to distributions as a whole. Statistical tests show that the cost-effectiveness of the second treatment scheme is significantly worse. Thus, the significantly lower cost-effectiveness of the second scheme compared to the first scheme is confirmed by the Kolmogorov test with statistics D = 0.58954, p = 4.281e-11 and Fisher's test 0.6309457, with p<0.0001. There were no significant differences in the distributions of the cost-effectiveness index of the first and third treatment schemes.

Allocative efficiency of treatment schemes based on basic therapy. All studied schemes have optimal allocative efficiency, that is, the best combination of the sizes of the main and accompanying therapy. Moreover, not a single "tail" (slack) was observed for any patient, that is, there were no discrepancies in the sizes (disproportions) of the prescriptions of the volumes of the main and accompanying therapy. That is, in most cases, both the main and supporting therapy were used in excessive amounts, as was established above, but the excess was proportional.

Analysis of factors that significantly modified the cost-effectiveness criterion according to treatment schemes. We determined the factors that significantly modified the cost-effectiveness criterion according to treatment schemes, as the influence of the factors can be different. Such factors were: age and gender of the patient, place of residence (village; city), employment, length of stay in the hospital, diagnosis (BA; COPD), year of observation. Of all the criteria, we chose cost-effectiveness as multi-spatial and, therefore, the most informative.

The results of regression work are shown for the first and second treatment schemes, respectively, in Tables 3 and 4.

Журнал «Перспективи та інновації науки»
(Серія «Педагогіка», Серія «Психологія», Серія «Медицина»)
№ 11(45) 2024

Table 3.

Analysis of the influence of factors on the cost-effectiveness of the first treatment scheme by tobit regression.

Effect	Coefficient	Error	z	p
Constant	-0,1062	0,2604	-0,4080	0,6833
Age	0,0028	0,0030	0,9230	0,3560
Sex	-0,1210	0,1042	-1,1618	0,2453
Living in the village	-0,0572	0,0721	-0,7939	0,4272
Employment	-0,0065	0,0226	-0,2855	0,7753
Duration of inpatient treatment	0,0040	0,0158	0,2535	0,7999
Diagnosis	0,0720	0,0927	0,7767	0,4373
Year	0,1267	0,0292	4,3387	1,43E-05
Log(scale)	-1,4896	0,0990	-15,0445	3,75E-51

From Table 3, it is clear that the only included factor with a significant impact is the year of observation. From the positive value of the regression coefficient, it follows that the cost-effectiveness of the first scheme has improved over the years from 2019 to 2024.

Table 4.

Analysis of the influence of factors on the cost-effectiveness of the second treatment scheme by tobit regression.

Effect	Coefficient	Error	z	p
Constant	0,4950	0,2267	2,1831	0,0290
Age	0,0005	0,0029	0,1830	0,8548
Sex	0,1269	0,0607	2,0893	0,0367
Living in the village	0,0702	0,0565	1,2432	0,2138
Employment	0,0301	0,0298	1,0097	0,3127
Duration of inpatient treatment	0,0001	0,0103	0,0117	0,9907
Diagnosis	-0,0636	0,0639	0,9951	0,3197
Year	-0,0733	0,0282	2,5983	0,0094
Log(scale)	-1,3672	0,0754	18,1385	1,58E-73

The analysis of the influence of factors on the cost-effectiveness of the second treatment scheme by Tobit regression shows that during the observation years from

Журнал «Перспективи та інновації науки»
(Серія «Педагогіка», Серія «Психологія», Серія «Медицина»)
№ 11(45) 2024

2019 to 2024, the cost-effectiveness of the second scheme decreased, α=-0.0733, p=0.0094. The scheme worked better according to the cost-effectiveness criterion in male patients, α=0.1269, p=0.0367. All other considered factors did not have a significant impact on the cost-effectiveness of the second treatment regimen.

A comparison of the efficacy and safety of triple inhaled therapy (SITT) with dual bronchodilator therapy (DBT) in GOLD E COPD patients and those with frequent exacerbations showed that SITT was associated with a reduced risk of exacerbations compared to DBT, a reduction in the risk of exacerbations of approximately 20 % in patients on SITT. SITT has also been found to have a comparable safety profile to DBT, supporting the feasibility of its use in patients with severe COPD who have frequent exacerbations [9]. A meta-analysis of the effectiveness of triple therapy (inhaled corticosteroid, long-acting β2-agonist, and long-acting muscarinic receptor antagonist) with mono- and dual therapy with long-term bronchodilators for patients with COPD showed that triple therapy significantly reduced the risk of exacerbations by 29% compared with dual therapy and 46% compared to monotherapy. In addition, triple therapy has been shown to improve patients' quality of life and forced expiratory volume in the first second (FEV1) more effectively than other therapy options [10].

In a study by Kupryś-Lipińska et al. [11] evaluated the effectiveness of the Polish program for the treatment of severe allergic asthma using omalizumab. The results showed that 68% of patients had a significant reduction in the frequency of exacerbations, and 43% achieved an improvement in quality of life indicators. A 63% reduction in the number of hospitalizations was also noted, which emphasizes the effectiveness of omalizumab in real clinical practice. A review of the cost-effectiveness of asthma therapy, which includes a cost-benefit analysis of different treatment options, found that inhaled corticosteroids in combination with β2-agonists are more cost-effective than monotherapy, reducing hospitalization costs by up to 60%. In addition, for patients with severe asthma, omalizumab has shown good cost-effectiveness, especially in cases where the costs of hospitalization and other medical services are reduced [12].

Conclusions. The results of the study indicate that the most effective treatment scheme according to Farrell's criterion is the third scheme, however, its application is limited by a small number of patients in the sample, which calls into question the generalizability of the obtained results. The first scheme showed consistently high results in terms of technical efficiency among centiles of the index distribution, which indicates its superiority over the second scheme in the study conditions. The cost-effectiveness analysis confirmed the impracticality of using the second scheme, as its cost-effectiveness is significantly lower compared to other schemes, and has also significantly decreased in recent years. Therefore, when considering the economic efficiency of therapy for patients with BA and COPD, preference should be given to the first scheme that combines stable efficiency with acceptable cost indicators.

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