### Computer electroacupuncture in the treatment of bronchial asthma: clinical and economic efficiency A.B. Sands1, M.P. Khokhlov1, I.R. Kerov2

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## SUMMARY

- clinical and economic analysis of the effectiveness of computer research Target electroacupuncture (CEAP) for bronchial asthma (BA). The study included 80 BA patients. The patients were divided into equal-sized main (O) and reference (R) groups. CEAP was included in the treatment of patients in group O, patients in group P received isolated pharmacotherapy. We used the "KES-01MIDA hardware-software complex for electropunctural stimulation". Three monthly courses of CEAP were conducted, consisting of five sessions, carried out daily. In dynamics the parameters of bronchial patency were determined; consumption of fenoterol and beclomethasone; assessed the subjective status of patients (according to the AQ-20 and Spielberger-Khanin questionnaires). Clinical and economic analysis of the effectiveness of CEAP and pharmacotherapy was carried out with the determination of the costeffectiveness ratio (CER). According to the research, the use of CEAP in the complex treatment of asthma leads to an increase in bronchial patency, a decrease in fenoterol consumption by 30–40%, an increase in the quality of life index according to the AQ-20 questionnaire, and a decrease in actual and personal anxiety according to the Spielberger-Khanin test. It has been shown that the inclusion of CEAP in the complex therapy of asthma reduces the cost-effectiveness indicator by 3-4 times in comparison with isolated pharmacological therapy.

Keywords: computer electroacupuncture, bronchial asthma, clinical economic efficiency, biologically active points.

### Introduction

In recent years, there has been an increase in interest in the economic evaluation of the effectiveness of the treatment of various diseases. This is due, first of all, to the emergence of a wide range of alternative methods of therapy, a large number of expensive medical technologies and an increase in the cost of medical services [1, 2]. Today, there are more than ten methods of economic analysis of the effectiveness of therapeutic interventions. The main ones are cost minimization analisis, cost effectiveness analisis, cost utility analisis, cost benefit analisis and cost of illness analysis [3] ...

Bronchial asthma (BA) is a widespread disease, the treatment of which requires significant financial costs. Thus, in Russia, the total cost per BA patient is about 20 thousand rubles per year [4]. Most of the costs are spent on providing patients with anti-asthma drugs. Therefore, it is extremely important to reduce the pharmacological load on the body of a BA patient while maintaining the control of the disease [5]. To solve this problem, non-drug methods of treatment are widely used [6].

Such interventions include one of the types of reflexology - computer electroacupuncture (CEAP). The results of a number of studies indicate the effectiveness of CEAP in the complex treatment of BA patients [7, 8]. Clinical and economic analysis of the effectiveness of CEAP in BA seems to be relevant for solving the issues of planning the mass use of this additional therapeutic method.

## Materials and methods

The study included 80 BA patients (60 women and 20 men, aged 16–68 years). The BA diagnosis was verified according to the "National Consensus on Bronchial Asthma" [9].

The study excluded persons suffering from cardiac arrhythmias (constant form of atrial fibrillation, Wolff-Parkinson-White syndrome, atrioventricular block), tactile hypersensitivity, electric current intolerance, cancer, diseases of the blood system, any chronic diseases in the stage

decompensation, and persons with an implanted pacemaker.

All patients were randomly divided into two groups - O (main) and P (reference) - 40 people each. The groups turned out to be comparable in gender, age, severity of the course of the disease and the leading clinical and pathogenetic variant of AD. All patients who took part in the study received pharmacotherapy in accordance with the AD treatment standards [9], and patients received fenoterol as a short-acting  $\beta$ 2-agonist, and beclomethasone as a basic anti-asthma drug. The groups turned out to be comparable in terms of the average daily doses of anti-asthma drugs.

CEAP was included in the complex therapy of patients in group O, patients in group P received isolated pharmacotherapy. We used the "KES-01-MIDA hardware-software complex for electropunctural stimulation" (IES) produced by CJSC MIDAUS, Ulyanovsk. Three monthly courses of CEAP were conducted, consisting of five sessions, carried out daily in the morning. We used biaricular BAP schemes recommended by L.S. Pesikov and S. Ya. Rybalko [10].

The study design assumed a six-fold examination of each patient at the beginning and at the end of each of the three courses of CEAP in group O. Each of the examinations "programmed" in this way was defined by us as a "control point". The examination protocol at the first and sixth control points included: determination of the forced expiratory volume in the first second (FEV1) and functional vital capacity of the lungs (FVC); registration of qualitative and quantitative characteristics of pharmacotherapy at the time of examination (consumption of fenoterol and beclomethasone); quality of life test (according to the AQ-20 questionnaire); tests for assessing the indicators of the subjective state of patients (according to the Spielberger-Khanin questionnaire). Control points 2–5 assumed the registration of the consumption of anti-asthma drugs.

Clinical and economic analysis of the effectiveness of CEAP and pharmacotherapy was carried out with the determination of the cost-effectiveness ratio according to the formula:

CER = DC + IC / Ef,

where CER is the cost-effectiveness ratio (shows the costs per unit of efficiency); DC - direct costs; IC - indirect costs; Ef - treatment efficacy (change in the studied parameters during the observation period). Direct costs included the cost of anti-asthma drugs and the cost of CEAP sessions (for group O).

Determination of the cost of anti-asthma drugs was carried out by calculating the average daily doses of fenoterol and beclomethasone (in  $\mu$ g) at six control points. Then the total dose of the drug received by the patient during the study period was determined - the average daily dose was multiplied by the study duration (90 days). The resulting value of the course dose was multiplied by the cost of 1  $\mu$ g of the drug, thus determining the cost of the course dose. The average cost of the drug was calculated based on the price of the drug in pharmacies in Ulyanovsk. The cost of one CEAP session was taken at 150 rubles. (three courses - fifteen sessions - 2250 rubles).

The effectiveness of treatment was understood as the increments (absolute changes) of the clinically significant parameters under study. Comparison of the cost-effectiveness ratio of CEAP in the complex treatment of asthma with isolated pharmacotherapy was carried out by calculating the incremental cost-effectiveness index. This indicator was calculated using the formula:

where CERi is an indicator of the increment in cost effectiveness; DS<sub>1</sub> - direct costs in the treatment of patients in group O; IS<sub>1</sub> - indirect costs for patients of group O; DS<sub>2</sub> and IS<sub>2</sub> - respectively, direct and indirect costs for patients of group P; Ef<sub>1</sub> and Ef<sub>2</sub> - respectively, the effects of treatment in groups O and P. Statistical analysis of the data was carried out using the Statistica 6.0 system. The significance of differences was calculated using the Student's t-test (t-test for related and unrelated cases). Differences were considered significant at p <0.05.

# Results of the study Clinical

# effects of CEAP in asthma

The use of CEAP made it possible to significantly improve the parameters of bronchial patency in BA patients. As a result of three monthly courses, CEAP FEV of the 1st main group increased from  $65.1 \pm 4.2$  to  $75.4 \pm 4.6\%$  (p <0.01). FVC underwent similar changes. In patients of group P, these indicators did not change significantly during the study (Table 1).

Dynamics of indicators of the function of e	external respiration in patients ι	Inder observation (% of
	individual norm)	
	Группа О	Группа Р

Показатель № контрольн		Группа О		Группа Р	
	ле контрольной точки	$M \pm m$	Достоверность различий	M ± m	Достоверность различий
0.6.01	1	$65,1 \pm 4,2$	$\begin{array}{c c} 5,1 \pm 4,2 \\ 5,4 \pm 4,6 \end{array}  p < 0,01 \end{array}$	$66,0 \pm 4,2$	-p = 0,23
0ФB1 6	6	$75,4 \pm 4,6$		$67,9 \pm 4,4$	
AMOD II	1	$80,3 \pm 4,2$	0.02	$78,7 \pm 4,6$	0.00
ФЖЕЛ	6	$87,9 \pm 4,5$	p = 0,03	$79,9 \pm 4,3$	p = 0,29

The inclusion of CEAP in the complex therapy of asthma led to positive changes in the characteristics of the subjective state of patients, which is shown in the analysis of the results of using the AQ-20 and Spielberger-Khanin questionnaires. Thus, the quality of life index (QOL) in group O increased from  $4.3 \pm 0.6$  to  $7.7 \pm 1.0$  points (p <0.01). At the same time, QOL changes in group P were not statistically significant. A similar dynamics was noted in the analysis of changes in actual and personal anxiety, determined by the Spielberger-Khanin test (Table 2).

table 2

Dynamics of indicators of the	ne subjectiv	e state of	patients	under ob	servatio	on (by
ques	tionnaire A0	Q-20 and	Spielberg	ger-Hanin	test), p	oints

	№ контрольной	Группа О		Группа Р		
Показатель	точки	$M \pm m$	Достоверность различий	M ± m	Достоверность различий	
	1	$4,3 \pm 0,6$		$4,8 \pm 0,6$		
индекс качества жизни	6	$7,7 \pm 1,0$	p < 0,01	$5,4 \pm 0,6$	p = 0,40	
A	1	$47,5 \pm 2,0$	0.01	$48,2 \pm 1,4$	0.00	
Актуальная тревожность	6	$41,7 \pm 2,1^{\circ}$	p = 0.01		p = 0,08	
T	1	$50,0 \pm 1,5$	5	$50,7 \pm 1,1$	0.00	
личностная тревожность	6	$44.8 \pm 1.8$ $p < 0.01$		$50,6 \pm 1,2$	p = 0,33	

достоверное (р < 0,05) различие с группой Р по t-тесту для несвязанных случаев.</li>

Flow  $\beta_2$ -A short-acting agonist (fenoterol) in group O during the first course of CEAP decreased from 625.6 ± 72.9 to 489.7 ± 63.4 µg / day. (p = 0.04; Table 3). During the second and third courses of CEAP, the flow rate  $\beta_2$ -agonists continued to decline: to 410.3 ± 61.4 and 369.2 ± 58.2 µg / day, respectively. In group P, the consumption of short-acting  $\beta_2$ -agonists had a statistically insignificant (p> 0.05) tendency to decrease (Table 3). The consumption of average daily doses of beclomethasone in group O during the first course of CEAP decreased from 626.3 ± 89.3 to 585.0 ± 86.0 µg / day. (p = 0.03). During the second and third courses of the CEAP, the indicator did not statistically significantly change, but it maintained a downward trend. In group P, during the entire study period, the consumption of corticosteroids fluctuated within 400–600 µg / day and did not change statistically significantly (Table 4).

Table 3

Dynamics of the consum	ption of fenoterol by	patients under ob	servation (µg / day)
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		Группа О	Группа Р		
контрольные точки	M ± m	Достоверность различий	M ± m	Достоверность различий	
1	$625,6 \pm 72,9$		$610,3 \pm 71,3$		
2	$489,7 \pm 63,4^{\circ}$	$p_{12} = 0.04$	$627,9 \pm 75,6$	$p_{12} = 0.46$	
3	$471,1 \pm 66,1$	$p_{13} = 0.01$	$587,9 \pm 65,6$	$p_{13} = 0.22$	
4	$410,3 \pm 61,4$	$p_{24} = 0,1$	$568,2 \pm 65,1$	$p_{24} = 0,1$	
5	$425,6 \pm 71,7$	$p_{15} < 0.01; p_{35} = 0.43$	$513,6 \pm 66,4^{\circ}$	$p_{15} = 0.03$	
6	$369,2 \pm 58,2$	$p_{ze} < 0.01; p_{ze} = 0.08$	$576,5 \pm 67,7$	$p_{26} = 0.2$	

\* – достоверное (р < 0,05) различие с первой контрольной точкой по t-тесту для связанных случаев.</p>

Table 4

Beclomethasone consumption by patients under observation ( $\mu$ g / day)

		Группа О	Группа Р	
контрольные точки	M ± m	Достоверность различий	M ± m	Достоверность различий
1	$626,3 \pm 89,3$		$510,9 \pm 66,3$	
2	$585,0 \pm 86,0$	p <sub>12</sub> =0,03	$495,3 \pm 66,1$	p <sub>12</sub> = 0,13
3	$561,5 \pm 76,7$	p <sub>1,1</sub> =0,7	$498,3 \pm 65,1$	p <sub>13</sub> = 0,23
4	$547,4 \pm 72,6$	p <sub>24</sub> = 0,98	$540,6 \pm 57,8$	p <sub>24</sub> = 0,28
5	$547,4 \pm 75,2$	$p_{15} = 0.5; p_{35} = 0.75$	$572,7 \pm 63,0$	p, 5 = 0,27
6	$523,1 \pm 70,7$	$p_{ae} = 0.73; p_{ae} = 0.63$	$550,0 \pm 69,4$	p <sub>26</sub> = 0,3

\* – достоверное (p < 0,05) различие с первой контрольной точкой по t-тесту для связанных случаев.

Thus, the use of CEAP as part of the complex treatment of asthma makes it possible to increase bronchial patency, improve a number of indicators of the subjective state of patients, and reduce the need for short-acting inhaled  $\beta$ 2-agonists.

Clinical and economic analysis of the use of CEAP in the complex treatment of BA patientsTaking into account the average daily doses of anti-asthma drugs during the observation period, as well as the cost of treatment with the CEAP method, the costs of treating patients in both groups were calculated.

The cost of providing fenoterol was higher in group P, while the total cost of beclomethasone in the compared groups was almost the same. The total cost of treatment for patients in group O exceeded that in patients in group P by 1,724.4 rubles. (Table 5).

Table 5

	Direct costs	of treating a	BA patient of	during the ob	servation p	eriod, rubles
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Лечебное вмешательство	Группа О	Группа Р
Фенотерол	$1710,3 \pm 211,9$	$2199,6 \pm 241,1$
Беклометазон	$800,8 \pm 96,6$	$837,1 \pm 92,5$
КЭАП	2250,0	100
Общая стоимость лечения	4761,1	3036,7

A cost-effectiveness analysis of the treatment of BA patients with the CEAP method was carried out. Taking into account the costs of treatment (medication and treatment of CEAP) in comparison with the effectiveness of treatment, it turned out that the cost of an increase in FEV1 by 1% in group O was more than 2 times lower than that in group P. An even more significant difference between the compared groups was obtained in the analysis in the cost of increasing the indicators of subjective status by 1 point (tab. 6).

Table 6

Cost-Effectiveness Analysis (CER) of Quantitative Clinically Significant Indicators patients under observation, rub.

Показатель	Показатель соотношения «затраты/эффективность»		Инкрементный показатель соотношени	
	Группа О	Группа К	затрат и эффективности	
1 % прироста ОФВ1	350,1	820,7	174,2	
1 % прироста ФЖЕЛ	501,2	1597,9	226,9	
1 балл индекса качества жизни	1286,8	6073,4	538,9	
1 балл актуальной тревожности	865,7	2760,6	391,9	
1 балл личностной тревожности	898,3	3374,1	391,9	

The calculation of the incremental cost-effectiveness ratio (CERi) determined the amount of additional funds required to improve the studied indicators by 1 unit of measurement (%, points). The lowest CERi value was noted when calculating additional investments for a 1% increase in FEV1 - 174.2 rubles (Table 6).

### Conclusions:

1. The inclusion of CEAP in the complex treatment of BA patients leads to an increase in bronchial patency (an increase in FEV1 and FVC), a decrease in the consumption of inhalation  $\beta_2$ - short-acting agonists by 30-40% and an improvement in the characteristics of the subjective state of patients (in particular, an increase in the quality of life index according to the AQ-20 questionnaire, a decrease in actual and personal anxiety according to the Spielberger-Khanin test).

2. The use of CEAP in the complex therapy of asthma reduces the cost-effectiveness indicator in 3-4 times, compared with the reference group.

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