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RANDOMIZED CLINICAL TRIAL OF BRONCHIAL ASTHMA MANAGEMENT ALGORITHM

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During the last century asthma occasionally observed in clinical disease has become one of the most common, representing a serious threat to the health of humanity as a whole. The aim of the study was to evaluate the effectiveness of the asthma management algorithm. The study was conducted on the basis of patients at pulmonary department of the regional clinical hospital, Shymkent. The study group included 80 patients with bronchial asthma uncontrolled course, randomly selected. All statistical analysis procedures were performed using SPSS 20 and the SAS software. B during the analysis of all collected to monitor the effectiveness of the intervention indicators were obtained statistically significant differences in the groups. This fact indicates the presence of the clinical effectiveness of pilot implementation (training in asthma-school and issuance of personal peak flow meters) in the management of asthma in the outpatient and inpatient levels.

Keywords: a randomized clinical trial, asthma, clinical management.

РАНДОМИЗИРОВАННОЕ КЛИНИЧЕСКОЕ ИСПЫТАНИЕ АЛГОРИТМА МЕНЕДЖМЕНТА БРОНХИАЛЬНОЙ АСТМЫ

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В течение последнего столетия бронхиальная астма из редко наблюдаемой в клинической практике болезни стала одной из самых распространенных, представляющих серьезную угрозу здоровью человечества в целом. Целью исследования было оценить эффективность алгоритма менеджмента бронхиальной астмы. Исследование больных проводилось на базе пульмонологического отделения Областной клинической больницы и поликлиники клиники МКТУ г. Шымкент. В группу исследования вошли 80 больных бронхиальной астмой неконтролируемого течения, отобранных случайным образом. Все процедуры статистического анализа данных были выполнены с помощью программного обеспечения SPSS 20 и SAS. В ходе анализа всех взятых для контроля эффективности вмешательства показателей были получены статистически значимые различия в группах. Данный факт говорит о наличии клинической эффективности экспериментального внедрения (обучение в астма-школе и выдача персональных пикфлоуметров) в менеджмент бронхиальной астмы на амбулаторном и стационарном этапах.

Ключевые слова: рандомизированное клиническое испытание, бронхиальная астма, клинический менеджмент.

БРОНХИАЛДЫ АСТМАНЫҢ МЕНЕДЖМЕНТІ АЛГОРИТМІН РАНДОМИЗИРЛЕНГЕН КЛИНИКАЛЫҚ СЫНАҒЫ

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Соңғы жүзжылдықта бронхиалды астма клиникалық практикада сирек болатын аурулардың бірінен адамзат денсаулығына үлкен қауіп туғызатын өте көп тараған аурулардың бірі болып

табылады. Бронхиалды астманың менеджменті алгоритмі тиімділігін бағалау зерттеу мақсаты болды. Науқастарды зерттеу Шымкент қ. ХҚТУ Облыстық ауруханасы мен емханасы пульмонологиялық бөлімі базасында өткізілді. Зерттеу тобына бақыланбайтын ағым 80 бронхиалды астмамен ауыратын, кез келген үлгіде таңдалған 80 науқас кірді. Мәліметтердің статистикалық талдау барлық процедуралары SPSS 20 және SAS бағдарламалық қамтамасыз ету көмегімен орындалды. Көрсеткіштер араласулары тиімділігін бақылау үшін барлық алынған талдау барысында топтардағы маңызды стаистикалық өзгешеліктер алынды. Осы факт амбулаторлық және стационарлық кезеңдердегі бронхиалды астманың менеджментіне (астма-мектепте оқыту және жекеленген пикфлоуметрлерді беру) эксперименталды енгізулерінің клиникалық тиімділігінің болуы туралы айтады.

Негізгі сөздер: рандомизрленген клиникалық сынақ, бронхиалды астма, клиникалық менеджмент.

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Background. During the last century asthma occasionally observed in clinical disease has become one of the most common, representing a significant social problem, both for children and for adults [1,3,6]. This disease affects all countries, regardless of their level of development, but its prevalence varies between populations, even within the same country. It is clear that over the past 20 years the prevalence of this disease has increased markedly [2,5].

Statistical indicators in Kazakhstan, as a rule, based on data obtained from the use of health care, and do not reflect the true prevalence of the disease as the primary treatment is often due to the need for emergency medical interventions in patients who already have moderate or severe disease [8-11]. Consequently, we are dealing with an increase in cases of "uncontrolled" asthma. Based on the data of medical statistics, a paradoxical situation: one of the lowest rates of asthma in the world combined with a high level of temporary incapacity, disability, hospitalization, mortality.

Aim of study was to evaluate the effectiveness of the asthma management algorithm.

Materials and methods. A study was conducted on the basis of the pulmonary department of the regional clinical hospital and clinics of Regional Hospital, Shymkent. The work is based on comprehensive clinical-laboratory and instrumental examination of 80 patients with bronchial asthma uncontrolled flow, randomly selected. The intervention group (experimental) consisted of 40 patients with bronchial asthma, matched by sex and age with a control group of 40 patients, respectively.

Each patient as the admission by trained research assistant first issued a sealed envelope with an attached number. Two collections were selected randomly using the online random number generator (http://randstuff.ru/number/). With the opening of the envelope, the number of patients identified second assistant researcher of belonging to the intervention group or the control group. Neither the patient nor the first assistant did not know which group they are assigned, ensuring equal chances for each patient to get into any of the groups. Thus, we were recruited two groups of patients with a diagnosis of bronchial asthma for inclusion in the study.

All statistical data analysis procedures were performed using SPSS software version 20 for Windows and SAS. All personal data analytical forms filled in the study all patients were entered into SPSS data base and then import the database platform SAS.

Results and discussion. After all the preparatory procedures, we obtained the following data. To study for the reporting period was scored a total of 80 patients with moderate-severe uncontrolled (or partially controlled) asthma, which we assessed major clinical and

functional parameters be taken into account at the stage of entry into the study (1 point) and subsequent stages over time (2 or 3 points).

All patients examination and treatment started on the stationary phase. Clinical characteristics of all patients are presented in Table 1. In order to assess the dynamics of the initial and final figures in both groups, we took respiratory symptoms (cough, shortness of breath, wheezing), daily need to use SABA, asthma attacks during the last 4 weeks, lung function (PEF and PEF dynamics on the endpoint, FEV1), and the result of evaluation of ACT (Table 1).

Table 1.

The main characteristics and input estimates (point 1) the experimental and control groups of the study.

Characteristics	Experimental group (A)	Control group (B)	*p* – value
Number of patients	40	40	
Age, years (± SD)	48.6 (± 11.3)	49.5 (±12.5)	0.63
Sex			
Male, n (%)	13 (25.7%)	12 (29.3%)	0.34
Female, n (%)	27 (74.3%)	18 (70.7%)	
Disease duration, years (± SD)	8.9 (± 9.3)	9.1 (± 8.6)	0.55
Respiratory symptoms			
Cough, n (%)	40 (100.0%)	40 (100.0%)	n/a
Shortness of breath, n (%)	39 (97.5%)	40 (100.0%)	0.99
Wheezing, n (%)	31 (77.5%)	30 (75.0%)	0.81
SABA using a day (± SD)	6.3 (± 1.2)	6.5(± 0.9)	0.79
Asthma attack number (± SD)	8.5 (± 1.1)	8.9 (± 1.5)	0.78
Initial PEF, % of norm (± SD)	58.6 (± 4.4)	55.4 (± 5.8)	0.21
Dynamics of PEF (± SD)	23.2 (± 3.1)	24.1 (± 4.1)	0.710
Initial EFV1, % of norm (± SD)	47.4 (±6.1)	47.9 (± 5.3)	0.891
The test for bronchial reversibility (± SD)	20.9 (± 2.8)	22.3 (± 1.9)	0.833
Initial ACT (± SD)	16.1 (± 4.3)	16.7 (± 3.65)	0.897

As seen from Table 2, in comparison groups did not differ in overall identification characteristics and clinical data input. The average age of patients was 48.6 ± 11.3 years in group A and 49.5 ± 12.5 years in group B, respectively (p = 0.63). Gender distribution was also similar in the groups: male were 13 (25.7%) in the experimental group and 12 (29.3%) in the control group. Females accounted for 27 (74.3%), i18 (70.7%), respectively (p = 0.34). The average duration of the disease ranged in small range of 8.9 ± 9.3 to 9.1 ± 8.6 years (p = 0.55). The proportion of individuals with respiratory symptoms was in almost all cases (cough, shortness of breath, wheezing) in both groups more than 30% (p> 0.05). The daily requirement for using SABA in the intervention group was 6.3 ± 1.2 times a day, and in the control group – 6.5 ± 0.9 times a day (p = 0.79). Asthma attacks in the past 4 weeks in the experimental group were observed in average 8.5 ± 1.1 times in the control group – 8.9 ± 1.5 times (p = 0.78). Some PEF, expressed as a percentage of normal values in the group A was 58.6 ± 4.4%, in group B – 55.4 ± 5.8% (p = 0.21). Lability of PEF in both groups were from 23.2 ± 3.1 to 24.1 ± 4.1 (p = 0.71). The initial rate of FEV1, expressed as a percentage of normal in the experimental group was 47.4 ± 6.1%, in the control group – 47.9 ± 5.3 (p = 0.89). Test bronchial reversibility in the intervention group was 20.9 ± 2.8, and in the comparison group – 22.3 ± 1.9 (p = 0.83). Initial AST indicators in both groups were small oscillations in the range of 4.3 to 16.1 ± 16.7 ± 3.65 (p = 0.89).

After the analysis of the input data in the study (point 1, Table 2) patients of the experimental group was trained in the framework of the asthma schools designed specifically for research purposes (3 training unit). Each participant of the experimental group was provided a personal peak flow meter during the experiment. All patients continued on standard therapy regimens that

have been assigned during the initial consultation, or continue as planned. The main hypothesis of this phase of work was that the patients of the experimental group can after training self-diagnosis by determining PEF and lability PEF (keeping a diary asthmatic) will be able to better control asthma and as a result have fewer respiratory symptoms, exacerbations, requirements SABA and the best indicators lung function.

After 4 weeks (2 points) and 16 weeks (3 points) in both groups was registered dynamics of indicators of the daily requirement of using SABA, asthma attacks during the last 4 weeks, FEV1, PEF, fluctuations PEF(± SD), and the results of ACT (Table 2).

Table 2.

Intermediate and final evaluation (point 2 and 3) the experimental and control groups of the study.

Characteristics	Experimental group (A)	Control group (B)	*p* – value
SABA using a day (± SD)			
Second visit (± SD)	5.2 (± 1.1)	6.1 (± 1.9)	0.05
Third visit (± SD)	3.1 (± 0.8)	5.8 (± 1.3)	0.02
Dynamics between 2 and 3 (± SD)	2.1 (± 0.3)	0.3 (± 0.6)	0.001
Asthma attack number (± SD)			
Second visit (± SD)	7.1 (± 1.5)	8.0 (± 1.8)	0.34
Third visit (± SD)	3.1 (± 1.4)	7.9 (± 0.9)	0.04
Dynamics between 2 and 3 (± SD)	4.0 (± 0.1)	0.1 (± 0.9)	0.001
FEV1, % of norm (± SD)			
Second visit (± SD)	53.5 (± 5.2)	49.9 (± 3.3)	0.031
Third visit (± SD)	78.2 (± 6.3)	64.6 (± 7.9)	0.025
Dynamics between 2 and 3, %	24.7%	14.7%	<0.001
PEF, % of norm (± SD)			
Second visit (± SD)	68.6 (± 5.4)	59.5 (± 6.1)	0.002
Third visit (± SD)	76.4 (± 3.5)	63.1 (± 3.9)	0.001
Dynamics between 2 and 3, %	5.8%	3.6%	0.05
Lability PEF (± SD)			
Second visit (± SD)	21.3 (± 3.1)	24.1 (± 4.1)	0.04
Third visit (± SD)	19.1 (± 4.2)	23.2 (± 3.8)	0.04
Dynamics between 2 and 3, %	2.2%	0.9%	<0.001
ACT (± SD)			
Second visit (± SD)	18.6 (± 4.5)	17.8 (± 3.6)	0.06
Third visit (± SD)	22.5 (± 3.5)	19.5 (± 3.3)	0.005
Dynamics between 2 and 3, points	3.9	1.7	<0.001

The analysis of the intermediate and final assessments (point 2 and 3) the experimental and control groups, the study revealed dynamic changes in all parameters, with statistically significant differences in the comparison groups.

As follows from the data obtained in the experimental group patients in the interval between the second and third visits of the daily need to use SABA decreased almost twice. The differences in the dynamics of the reconciliation with the control group were statistically significant (p = 0.001).

Asthma attacks in the past 4 weeks in patients who have received training in asthma-school decreased from 7.1 to 3.1 on average, once a week, which was not achieved in the control group (p = 0.001).

Indicator spirography - FEV1 taken to control the dynamics of the Group of change in lung function increased significantly compared with the control group (<0.001), with 53.5% of normal during the second visit, to 78.2% during the third visit for consultation.

The analysis graphs PEF we observed high lability of this indicator between morning and evening measurements within 10 days of the initial observations. Thus there were statistically significant differences with the control group of

patients where the growth dynamics PEF was only 3.6% relative to the total increase in the base PEF from 68.6% to 76.4% in the intervention group throughout the study (p = 0.05), and fluctuations in PEF from 21.3 to 19.1 in the experimental group and from 24.1 to 23.2 in the control group (p = 0.04).

Of particular interest is the analysis of evaluation points ACT, given that one of the components of asthma education in school was to increase the commitment to control his condition with the help of a simple and valid tool. Dynamics between visits 2 and 3 for ACT scores in the experimental group was 3.9 and 1.7 in the control points, which is significantly inferior to the intervention (p <0.001).

Conclusion. In the study of the intervention effectiveness (asthma management algorithm) were obtained substantial, statistically significant differences in the groups. This fact indicates the presence of the clinical effectiveness of pilot implementation (training in asthma-school and issuance of personal peak flow meters) in the management of asthma in the outpatient and inpatient levels.

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