



ASIT AS THE COMPONENT OF BRONCHIAL ASTHMA'S THERAPY CAN IMPROVE THE ADHERENCE TO THE TREATMENT

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PRACA ORYGINALNA / ORIGINAL ARTICLE

ASIT JAKO ISTOTNY SKŁADNIK SKUTECZNEJ TERAPII
ASTMY OSKRZELOWEJ

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POLSKIE TOWARZYSTWO LEKARSKIE

SPIS TREŚCI NUMERU

TREATMENT
ALGORITHMS
OF PATIENTS
WITH
IMPACTION OF
MAXILLARY
CENTRAL
INCISORS
CAUSED BY
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Criteria of
economic
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Poland

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Abstract

The aim: To compare the treatment adherence of patients with Bronchial Asthma (BA) receiving basic treatment and its combination with allergen-specific immunotherapy.

Materials and methods: The study included 104 patients aged from 18 to 50 with BA. All patients were divided into two groups. The main group (MG) consisted of 51 patients receiving basic medical treatment and ASIT. 38 of them received subcutaneous ASIT and 13 patients received sublingual ASIT. The comparative group (CG) consisted of 53 patients who received only basic therapy. The patients' observation duration was for a year.

Results: All patients were done the computer spirometry with a bronchodilation test, determination of the total IgE level, questionnaires (quality of life, control of asthma, adherence to treatment). Also the major and minor component of allergy house dust mites and specific IgG4 were determined in patients of main groups. After 12 months of observation in both groups the spirometry rates improved (the main group result was 16.9%, the control group – was 12.8%). The indicators of asthma's control also increased (MG by 28%, in CG – 21%, ($p < 0.05$)). After individual conversations and training the patients improved and adherence to the treatment too.

In the beginning of our research the mean level in MG was 3.2 ± 0.3 points, in – CG- 3.3 ± 0.2 points ($p > 0.05$), after 12 months it increased to 6.3 ± 0.2 points in MG vs 5.8 ± 0.1 points in CG ($p < 0.05$).

infectious
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Więcej

Conclusion: Patients' combining basic therapy with SIT had significantly better results of the overall BA's controllability compared to the patients' receiving only basic therapy.

Streszczenie

Cel pracy: Porównanie przestrzegania zaleceń terapeutycznych u pacjentów z Astmą Oskrzelową (AO), którzy otrzymali podstawowe leczenie oraz ich połączenie z immunoterapią swoistą dla alergenu.

Materiały i metody: Badaniem objęto 104 pacjentów w wieku od 18 do 50 lat z AO. Wszyscy pacjenci zostali podzieleni na dwie grupy. Główna grupa (MG) składała się z 51 pacjentów otrzymujących podstawowe leczenie medyczne (wziewne kortykosteroidy lub długo działające połączenie β -agonisty / kortykosteroidu) i ASIT. 38 z nich (podgrupa 1a) otrzymywało tradycyjne podskórne ASIT, a 13 pacjentów (podgrupa 1b) otrzymywało podjęzykowe ASIT. Grupa porównawcza (CG) składała się z 53 pacjentów, którzy otrzymali tylko podstawowe leczenie. Czas obserwacji pacjentów wynosił rok.

Wyniki: Wszystkim pacjentom wykonano komputerową spirometrię z testem rozszerzania oskrzeli, określono całkowity poziom IgE wraz z kwestionariuszem (jakość życia, kontrola astmy, przestrzeganie leczenia). Określono także główny i drugorzędny składnik alergenów roztoczy prochu podstawowego i swoistej IgG4 u pacjentów z głównych grup. Po 12 miesiącach obserwacji w obu grupach poprawiły się wskaźniki spirometryczne (wynik grupy głównej wynosił 16,9%; grupa kontrolna – 12,8%). Wskaźniki kontroli astmy również wzrosły (MG o 28%, w CG – 21%, ($p < 0,05$)). Po indywidualnych rozmowach i szkoleniu pacjenci poprawili się i przestrzegali leczenia.

Na początku naszych badań średni poziom w MG wynosił $3,2 \pm 0,3$ punktu, w CG – $3,3 \pm 0,2$ punktu ($p >$

0,05), po 12 miesiącach wzrósł do $6,3 \pm 0,2$ punktu w MG w porównaniu do $5,8 \pm 0,1$ punktu w CG ($p < 0,05$).

Wnioski: Pacjenci łączący podstawowe leczenie z ASIT mieli znaczne lepsze wyniki ogólnej kontroli AO w porównaniu do pacjentów otrzymujących tylko podstawowe leczenie.

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INTRODUCTION

Bronchial asthma (BA) is an important medical, social and economic problem nowadays, as it causes disability and patients' quality of life (QL) decreases [1, 5, 9]. BA affects about 300 million people worldwide and it kills about 250 000 people a year. The prevalence of BA is increasing from year to year in the most countries. Also it leads to significant financial expenses [1, 5, 13]. The disease affects all age groups. The insufficient BA control leads to the significant deterioration of the patients' QL and to the death in some cases. So the main goal of BA treatment is achievement of the symptoms control. Despite of the large number of medicines for the BA treatment its' control is hard achievable [1, 8]. According to the latest recommendations of the GINA 2017, bronchial asthma therapy is based on a series of three consecutive steps: the symptoms assessment, the therapy appointment and the evaluation of the patient's response to the prescribed treatment. The important role in the remission's achieving is given by hypoallergenic diet and elimination measures. The inhaled corticosteroids (IC) are necessarily included in the bronchial asthma treatment. In patients with a persistent bronchial asthma the use of long-acting β_2 agonists (salmeterol, formoterol) is obligatory. Using the combinations containing an inhaled corticosteroid and a long-acting bronchodilator (salmeterol / fluticasone, budesonide / formoterol, betamethasone

/ formoterol) are preferred. If it is necessary, it is possible to use anti-leukotriene drugs, anti-IgE, anti-IL-5, short-term using of theophyllines, combined bronchodilators (ipratropium bromide / phenoterol). To relieve an attack patients use short-acting β_2 agonists (salbutamol, fenoterol), or a combination of budesonide / formoterol (Symbicort) in SMART mode.

As an additional treatment method, allergen-specific immunotherapy (ASIT) is used. ASIT is not included in the first line of drugs administration for the treatment of bronchial asthma. But it is recommended to use it if it is impossible to eliminate allergen. However, many randomized trials have shown that this method of treatment can reduce clinical manifestations and even achieve long-term remission in some patients.

Allergen-specific immunotherapy (ASIT) underuse in particular. The last one results not only in decrease of the sensitivity to the "causing" allergen but also reduces the chronic inflammation activity [4, 11].

ETIOLOGY

The house dust is the leading trigger factor in the BA exacerbation. Especially their most aggressive components are mites (*Dermatophagoides pteronyssinus* and *Dermatophagoides farinae*). About 150 species of mites are distinguished nowadays [4, 11, 20]. Acarofaunas' composition and its' season dynamics of dwellings are explored actively. Allergy induced by house dust mites is considered as a year-round allergy. There is some research state the increase by 2-3 times mites concentration in dust in late autumn compared to average annual values [21]. It's caused by the creating of ideal conditions for their growth and reproduction (increased humidity, reduced ventilation in the dwelling, turn on the heating). The mites are established not to possess the allergenic activity themselves as they are too big but their particles up to 0.05 mm possess. In particular mites' fragments and their feces containing their digestive enzymes provoke BA exacerbation. Hence the first two rise in the air simply and reach the airways [20]. Therefore, allergen-specific therapy is

paid special attention nowadays as it possess direct influence to the disease pathogenesis.

ASSESSMENT OF THE TREATMENT EFFICACY

We use to estimate the treatment efficacy by taking note only laboratory or instrumental research in practice. But we don't consider such important indicators as QL and adherence to the treatments which are closely related [2].

BA is a chronic disease affecting the patients' physical activity and modifying his lifestyle. Patients' QL estimation lets to get information not only on the patients' attitude to his disease but also how he evaluates the effectiveness of his treatment. The QL assessment implementation is reasonable as some of the treatment effects can be determined only by patients and standardized assessment is more credible than an informal conversation [2, 13, 17].

It joins issue of the wording of definition "adherence to the treatment" for many years. "Adherence to the treatment" characterizes how exact and consecutive patient follows doctors' recommendations as for medication, diet and lifestyle modification according to the WHO experts' definition. Special attention is paid to the active participation of the patient in the treatment [10, 13].

THE AIM

The aim of the study was to compare the treatment adherence of patients with BA receiving basic treatment and its combination with allergen-specific immunotherapy.

MATERIALS AND METHODS

The study included 104 patients aged from 18 to 50 with atopic BA mild intermittent, mild persistent and moderate persistent level. All patients were divided into two groups. The main group (MG) consisted of 51 patients receiving basic medical treatment (inhaled corticosteroids or long-acting β -agonist/corticosteroid

combination) and ASIT. 38 of them (subgroup 1a) received traditional subcutaneous ASIT and 13 patients (subgroup 1b) received sublingual ASIT. The comparative group (CG) consisted of 53 patients who received only basic therapy.

The patients' observation duration was for a year. It consists four visits: the first was at the inclusion in the research then 3, 6 and 12 months later. The groups were comparable in age, sex and severity of disease at the start of the study. All the patients were measured serum total IgE concentration and performed prick tests for the determination of the caused allergens. Efficacy of treatment was assessed by spirometry (FEV1 and peak expiratory flow (PEF)), asthma control test (ACT) and adherence to treatment questionnaire. Individual interviews with patient were conducted at each visit. The patients were told about the diseases' peculiarities, the prolonged treatment necessity, possible drugs side effects and way to act if the last one occurs. Possible factors of poor adherence were determined and were taken into consideration for the ongoing treatment.

We used the ACT for asthma controllability determination. It consists of 5 questions. The answers are rated from 1 to 5 points. Total asthma-score can be ranged from 5 to 25 points. The sum 15 points or less was considered as the sign of lack control over asthma, 16-19 points as partial control, and 20 points or more as well controlled asthma [1, 5, 13].

A lot of attempts are made to create questionnaires dedicated for assessing patients' adherence to treatment in recent years. The main problem while their creating is the difficulties in developing scale which would quantify the index. The first questionnaires allowing assessment patients' adherence to the treatment were developed by D.Morisky. Nowadays different modification of the questionnaires are worked out for plenty of chronic diseases. They allow to assess not only patients' following physicians' recommendations, but also to analyze patients' attitude to his disease, his mood and faith in the success of the treatment [5, 15, 17].

Adherence to the treatment was determined by means of the questionnaire designed by us. It consists of the seven questions which had to be answered by the patient oneself. They are: Do you have any doubts of the necessity for long-termed using of drugs treating your disease? Do you forget to take prescribed medicines regularly? People don't take medicines not only because the oblivion occasionally. Can you collect, if it was at least one day when you didn't take medicine during the last two weeks? Have you ever paused medicines admission due to their side effects without consulting with your doctor? Do you forget to take the medicines with you anytime when you go out home or travel? Do you have troubles with using inhalers? Have you any doubts about the correctness of the chosen treatments' strategy anytime?

The possible answers were "yes / no". The "Yes" response showed presence of the problems of the patients' implementation of the doctors' recommendations. The patient received 1 point for every "no" and for every "yes" 0 points. High adherence to treatment was considered if a patient got 7 points, medium 6-4 points, poor less than 4 points.

We conducted individual interviews of the necessity of the prolonged treatment, we told about the possible side effects and we checked the technique of the inhaler using also every visit.

RESULTS

The average patients' age was 32.6 ± 0.9 , 31.1 ± 1.4 in the MG and 34.1 ± 1.3 in the CG ($p < 0.05$). The groups were similar in the BA severity (Table I).

The asthma atopy was confirmed by the patients' total IgE serum level. It was higher than normal (100 IU / ml) in all the patients and it was more than 1,000 IU / ml in the 7 patients (Fig. 1). Most of patients (68%) had the total IgE level near 150-300 IU/ml (Fig. 1).

Specific allergic testing was performed by means of scarification and prick tests with a set of standard household allergens (a mixture of household allergens and/or dust mites *Dermatophagoides pteronyssinus* and *Dermatophagoides farina*) produced by "Immunolog" (Ukraine) and "Sevafarma" (The Czech Republic). The results revealed an increased sensitivity to the house dust and its components in all the patients (Table II).

Computer spirometry was conducted in all the patients. Basic parameters were determined (FEV1, PEF, FEV1/FVC = Index Gaensler, Forced vital capacity (FVC)) and bronchodilator test was performed. The average of FEV1 weren't different significantly between both groups at the first visit ($72.4 \pm 0.8\%$ and $72.6 \pm 0.7\%$, $p > 0.05$), FEV1 increased to $77.9 \pm 0.7\%$ in the MG and group to $78.1 \pm 0.7\%$ ($p > 0.05$) in the CG in 3 months. The Positive dynamics were observed after 6 (MG $85.1 \pm 0.4\%$ and CG $81.9 \pm 0.4\%$, $p < 0.05$) and 12 months of treatment ($87.1 \pm 0.4\%$ vs $83.3 \pm 0.4\%$, $p < 0.05$). Thus, significantly higher FEV1 values were observed in the MG on the third and the fourth visits. The increase and the difference between the groups were similar to FEV1 in the other spirometry indexes.

ASTHMA CONTROL TEST

The index of ACT was 15.1 ± 0.2 points in the MG and 15.5 ± 0.1 points in the CG ($p > 0.05$) at the research beginning. Thus, both groups demonstrated low controllability of asthma and there were no significant difference between the groups in the initial phase of the study. The dynamics of asthma controllability according to ACP is presented in Table III.

We compared separately ACT indexes during the treatment also. Nocturnal symptoms' frequency improved the fastest. The index control increased by 48.4% in the MG while by 29.0% in the CG in 12 months of treatment. Daytime symptoms controllability increased by 56.2% in the MG and by 38.5% in the CG in 12 months. Controllability of

breathlessness attacks increased by 36.7% and 35.7% respectively

ADHERENCE TO THE TREATMENT

The patients' adherence to the treatment was understudied also. The adherence to the treatment was poor in both groups at the beginning of the study (3.2 ± 0.3 points in MG vs. 3.3 ± 0.2 points in CG, $p > 0.05$). The patients' adherence to the treatment increased almost equally in both groups after three months of follow-up (4.1 ± 0.1 points vs 4.0 ± 0.1 points, $p > 0.05$). The increase of adherence index was observed in both groups in six (4.5 ± 0.1 points to 4.2 ± 0.3 points, $p < 0.05$) and 12 months of follow-up (6.3 ± 0.2 points to 5.8 ± 0.1 points, $p < 0.05$). As you can see the adherence to the treatment was significantly higher in the patients receiving SIT than in the CG in 6 and 12 months of therapy. So the adherence increased by 96.9% in the MG while by 75.8% in the CG in 12 months of follow-up.

We also compared the adherence of the MG's patients treated by subcutaneous (Ia) or sublingual (Ib) SIT methods. The patients' adherence to the treatment was poor according our own questionnaire at the study beginning (3.3 ± 0.1 points in Ia subgroup vs. 3.2 ± 0.1 points in Ib subgroup, $p > 0.05$). The adherence index was better in the patients receiving subcutaneous SIT in 3, 6 and 12 months of the treatment (6.3 ± 0.2 points vs 5.8 ± 0.1 points, $p < 0.05$) (Fig. 2).

It can be explained by several disadvantages of subcutaneous SIT (permanent visits to allergy clinics, everyday subcutaneous injections) influencing on the patients' daily routine and his adherence to the treatment.

Changes in the treatment regimen

The daily inhaled corticosteroids/ long-acting β_2 -agonists dose have been (was) reduced in most of the MG's patients (68.6%) during the follow-up. That affected positively to the adherence to the treatment.

There was no need to increase doses of the medicines in that group also. But only 6 patients (11.3%) from the CG were reduced the daily dose ICS and the basic medicines' enlargement was been necessary in 12 (22.6%) patients. The dosage reducing can be explained by that the combined use of pharmacotherapy and SIT not only controls the inflammation but also allows developing the tolerance to the specific allergens by gradually increasing their doses. The drugs quantity's reducing also had positive impact on the adherence to the treatment.

DISCUSSION

Although there are a plenty of the medicines for BA treatment now but we can't to achieve the BA's control in some patients. The well-controlled asthma is considered if the symptoms don't affect the normal patients' rhythm of life, don't wake him at night and don't disturb to perform his necessary work.

It is necessary to examine the patient and to prescribe the effective treatment for achievement the good controllability of the disease. SIT with disease-causing allergens should be added to the basic treatment of patients with atopic BA. That improves the controllability of the disease, the respiratory function parameters and the treatment's adherence. Non-invasive regimen of SIT is better to use particularly sublingual. It's easy to use, doesn't require frequent visits to the doctor, less likely causes local or systemic allergic reactions improving the adherence to the treatment and increasing their effectiveness.

Patients' adherence to the treatment is an important component of the effective therapy. The reasons for poor adherence can be divided into two main groups. The first group is associated with medicines administration (difficulties with inhaler devices, complicated treatment regimens, side effects and cost of the drugs, remoteness of pharmacies) [14]. BA is a chronic disease. So the patients should administered permanently or long time some

medicines (inhaled corticosteroids, bronchodilators, anti-leukotriene agents) creating some inconvenience. Another big problem is the distrust to the physician or poor contact with him. The last ones were caused by the prescription of the complex treatment without sufficient explanation of the drugs benefits and side effects, neglecting the cost of the medicines and the patients' ways of life. That leads to the disturbance in treatment regimens, reducing the dosage or frequency of the medicines administration and further reducing of the treatment efficacy. The easy dosage (one tablet or one inhalation per day) helps to achieve better adherence.

It is important to identify factors affecting the "nonadherence" to the treatment additionally to the adherence monitoring. The psychological problems (depression), the side effects of the drugs, reduction or complete absence of the disease symptoms, misunderstanding of the disease by patient, lack of the faith in the treatment effect, distrust to the doctors, the cost of treatment and the difficulty for getting to the clinics are the mains of them.

The individual interviews should be conducted in order to improve the adherence. Special attention (on it?) should be paid to the causes and features of chronic diseases, to the necessity of the long-term treatment, to the possible complications in the cause of no-adherence and side effects that may occur during the treatment and ways to act in such situations. The patient's age and his ways of life should be taken into account.

CONCLUSIONS

Patients' combining basic therapy with SIT had significantly better results of the overall BA's controllability compared to the patients' receiving only basic therapy. Adherence of treatment was significantly better in the MG too.

The method of SIT had significant impact on the adherence to the treatment. Patients receiving sublingual SIT were observed significantly higher

improvement of its level. The especial convenience of this method was noticed by the patients. There was no need for frequent visits to the hospital for SIT first of all. It not only saved the time, but also ensured some psychological comfort.

Improvement of the BA's control and QL led to the improved patient's adherence to the treatment.

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Zaakceptowano: 14.05.2018

Table I. The patient's distribution by disease severity.

BA severity	Main group		Comparison group	
	Quan tity	%	Quanti ty	%
Mild intermittent	11	21 ,6	13	24, 5
Mild persistent	17	33 ,3	18	34
Moderate persistent	23	45 ,1	22	41, 5

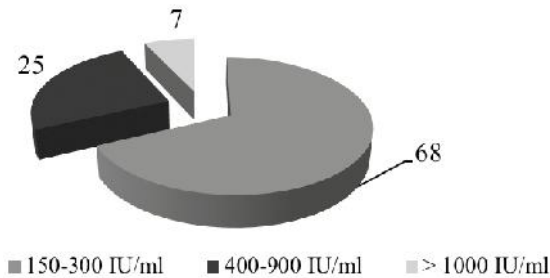


Fig. 1. The total IgE serum level.

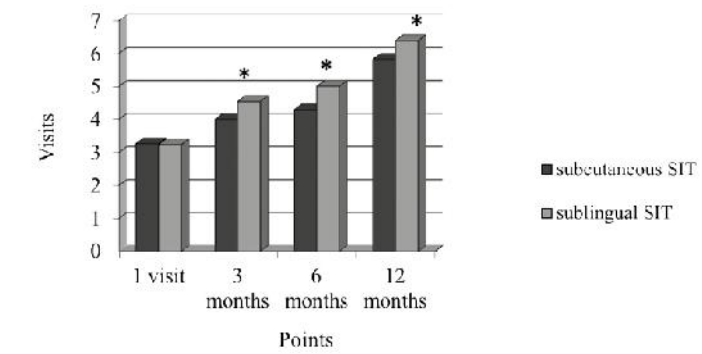
Table II. The frequency of the household allergens sensitization according to the skin allergy testing (n=104)

Allergen type	Positive tests (the absolute value)	Positive tests percentage [%]
House dust, Dermatophagoide s pteronyssinus	98	94.2
House dust, Dermatophagoide s farinae	76	73.1
House dust, Dermatophagoide	37	35.6

s acarus siro		
Pillow feather	42	40.4
Dog hair	41	39.4
Cat hair	49	46.2

Table III. Dynamics of asthma controllability indicator.

	First visit (including in the study)	Seco nd visit (3 mont hs)	Thir d visit (6 mo nth s)	Fourt h visit (12 mont hs)
Main group	15,4 ± 0,4	17,8 ± 0,3	18,2 ± 0,1	21,4 ± 0,4
Compari son group	15,3 ± 0,2	17,2 ± 0,2	17,8 ± 0,1	19,4 ± 0,3
p	> 0,05	< 0,05	< 0,05	< 0,05



* – the difference between subgroups Ia and Ib was statistically significant (p <0.05).

Fig. 2. The evolution of the patients' adherence to the treatment

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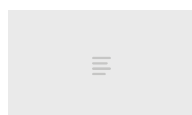
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Criteria of economic
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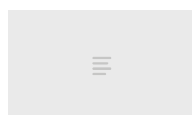
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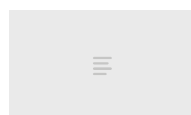
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**Screening
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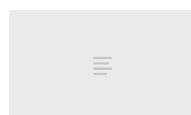
16 lipca 2018



**PATHOGENE
SIS OF
INSULIN
RESISTANCE
IN**

**PREGNANT
WOMEN
WITH
OBESITY**

16 lipca 2018



**PREVENTION
OF
VENTILATOR
-
ASSOCIATED**

**PNEUMONIA
IN
NEWBORNS**

16 lipca 2018

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