Original paper

Clinical profile of chronic bronchial asthma patients in Poland: results of the PROKSAL study

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Abstract

Introduction: Asthma is a complex condition characterized by the presence of chronic inflammation in the lower respiratory tract resulting in many disturbing symptoms. The study of the clinical profile of the population with asthma allows us to understand a trend of a specific disease taking into account several indicators and its clinical characteristics.

Aim: Evaluation of the clinical profile of patients with chronic bronchial asthma in Poland.

Material and methods: The study included 10400 adult patients, of both sexes, diagnosed with chronic bronchial asthma who started therapy based on inhaled glucocorticosteroids accompanied by salmeterol, and 52 allergists. The examination was performed in a doctor's surgery. Standardized questionnaire interviews were used in order to carry out the procedure.

Results: The age of the patients ranged from 18 up to 97 years. Most of them suffer from overweight and obesity. 45.3% of the patients smoked cigarettes or declared to be passive smokers. Current asthma control was poor: over 56% of the patients suffered from diurnal symptoms more often than twice a week, almost 55% from nocturnal symptoms, in 72% of the patients' physical activity was limited, whereas 57% required immediate treatment. Most commonly used drugs were inhaled glucocorticosteroids and short acting β2-mimetics. After treatment change, fewer patients suffered from asthma symptoms.

Conclusions: Adjusting the therapy according to the current guidelines and to the patient's needs helps to improve asthma control.

Key words: asthma, clinical profile, PROKSAL, allergy, inhaled glucocorticosteroids.

Introduction

Asthma is one of the fastest-spreading diseases of the 21st century. It is a complex condition characterized by the presence of chronic inflammation in the lower respiratory tract, deriving from variable airflow obstruction and airway hyperresponsiveness and resulting in recurrent episodes of coughing, wheezing, shortening of breath and tightness in the chest. It is estimated that by 2020 half of the population will suffer from asthma [1, 2]. Despite increasing awareness and knowledge as well as improving methods of the disease treatment, it has been spreading vigorously since late 20th century. According to the World Health Organization (WHO), around 300 million people suffer from chronic bronchial asthma (CBA) worldwide, while in Poland it is about 4 million people although even half of them may have not been diagnosed [3].

The research on the profile of the population suffering from asthma allows us to understand a trend for this disease taking into account several indicators and the clinical characteristics of asthma.

Aim

The aim of the study was to evaluate the clinical profile of patients with chronic bronchial asthma in Poland, the progress of the disease and its control.

Material and methods

PROKSAL was the real-life research that meets the criteria of a "non-interventional study" specified in Directive 2001/20/EC – Article 2(c) ("a study where the

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medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data"), the Pharmaceutical Law Act and the Code of Good Marketing Practices of the Pharmaceutical Industry, Cooperation with Health Care Representatives and Patient Organizations.

Study population

The study population included 10 400 patients of both sexes. The inclusion criteria for participants were as follows: CBA diagnosis, ≥ 18 years old and starting treatment with salmeterol accompanied by inhaled glucocorticosteroid (iGC). The participants were included on a non-random basis, following an independent decision of the doctor, based on the treatment method. The detailed inclusion and exclusion criteria can be found in Table 1. Verbal consent was obtained from all the patients in the research project.

The study included 52 allergists registered by relevant district medical councils and holding the licence to practice the medical profession which was not suspended or limited as regards performance of specific medical activities.

Study time and territory

The study lasted for 3 months from February 2013 to April 2013. The completed study was an open-label, multicentre trial carried out in doctors' surgeries throughout the whole Poland.

Research method

The examination was performed during patients' appointments in a doctor's surgery. Standardized questionnaire interviews available on the Internet platform were filled in by the allergists based on observation and conversation with the patients in order to carry out the research. A standardized research tool in the form of intelligence questionnaires made the results comparable and normalized.

Table 1. Inclusion criteria for patients

Inclusion criteria for patients		Exclusion criteria for patients	
Age	≥ 18	Subjects diagnosed with obstructions involving large airways:	Foreign body in trachea or bronchus; vocal cord dysfunction; vascular rings or laryngeal webs; laryngotracheomalacia, tracheal stenosis or bronchostenosis; enlarged lymph nodes or tumour
Diagnosis	Chronic bronchial asthma	Subjects diagnosed with obstructions involving small airways	Viral bronchiolitis or obliterative bronchiolitis; cystic fibrosis; bronchopulmonary dysplasia
Recommended treatment	Salmeterol + iGCs	Other causes	Recurrent cough not due to asthma; aspiration from swallowing mechanism dysfunction or gastroesophageal reflux; chronic obstructive pulmonary disease; congestive heart failure; pulmonary embolism; pulmonary infiltration with eosinophilia; vasculitis involving the lungs and airways; post-transplant patients
Consent	Oral consent		

iGCs – inhaled glucocorticosteroids.

Table 2. Levels of asthma control according to GINA

Characteristic	Levels of asthma control		
	Controlled	Partly controlled	Uncontrolled
Daytime symptoms	Twice or less a week	More than twice a week	Three or more features of partly controlled asthma
Nocturnal symptoms	None	Any	
Limitation of activities	None	Any	
Need for reliever	Twice or less a week	More than twice a week	
Lung function (FEV_1 or PEF)	Normal	Less than 80% of predicted or personal best	

FEV_1 – forced expiratory volume in one second, PEF – peak expiratory flow.

Table 3. Age statistics

Age statistics		Value [years]
Mean		51.85
Standard deviation		16.64
Median		54
Mode		60
Range	Min.	18
	Max.	97
Quartiles	25%	40
	50%	54
	75%	64

In Table 2 levels of asthma control accoridng to GINA are presented. In Appendix we presenting the questionnaires utilized for visit 1, 2, and 3.

Statistical analysis

Data are presented as descriptive statistics.

Results

Sex and age

The sample included both sexes, males (45.3%) and females (54.7%). The mean age ± range in the study group was 51.85 ±16.64 years. The dominant age among the patients was 60 years. The youngest participant was 18 years old, the oldest one was 97. The largest number of patients were between 56 and 65 years of age (Figure 1). More details about age statistics can be found in Table 3.

Weight/body mass index

Body mass index (BMI) was estimated during the study. Within 35.7% of the survey population, BMI was 18.5–24.9 kg/m^2, in 43.3% of the participants BMI was 25–29.9 kg/m^2, in 19.4% BMI was higher than 30 kg/m^2. The detailed distribution of BMI among the study group is presented in the bar chart (Figure 2).

Blood pressure and heart rate

The data collection showed that 34.7% of the patients had BP of 120–129/80–84 or < 120/< 80. In total, 22.4% of the participants had BP higher than 130/85. The details about BP distribution and the hypertension classification among the study group are presented in Table 4. The mean value ± SD of the heart rate in the study group was 78.42 ±8.87 heartbeats per minute (hbs/min). The most numerous group included patients with 80 hbs/min (dominant). The lowest heart rate was 48 hbs/min, whereas the highest 199.

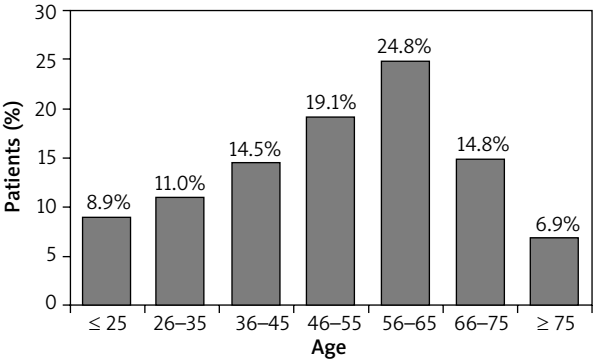

Figure 1. Age among the study group. Up to 65 years of age the number of participants increases with age. The least numerous groups were patients younger below 25 and over 76 years

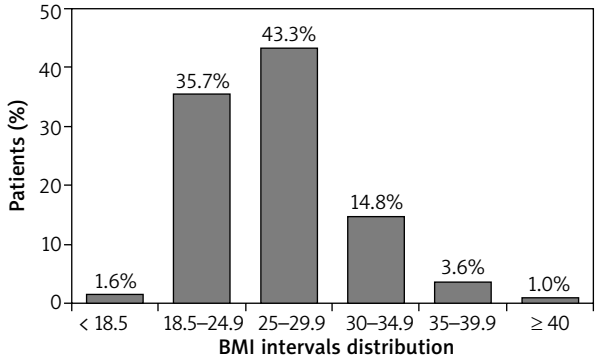

Figure 2. Body mass index (BMI) distribution among the study group. Most of patients had BMI between 25 and 29.9 kg/m^2

Table 4. Distribution of blood pressure in the study group

Status according to the ESH/ESC classification	Arterial blood pressure [mm Hg]	Percentage of study population
Optimal blood pressure	< 120/< 80	8.3
Normal blood pressure	120–129/80–84	26.4
High normal blood pressure	130–139/85–89	25.7
First degree hypertension	140–159/90–99	18.4
Second degree hypertension	160–179/100–109	3.6
Third degree hypertension	≥ 180/≥ 110	0.4
Isolated systolic hypertension	≥ 140/< 90	17.2

The patients were divided into groups by their blood pressure (BP) based on the ESH/ESC classification [40].

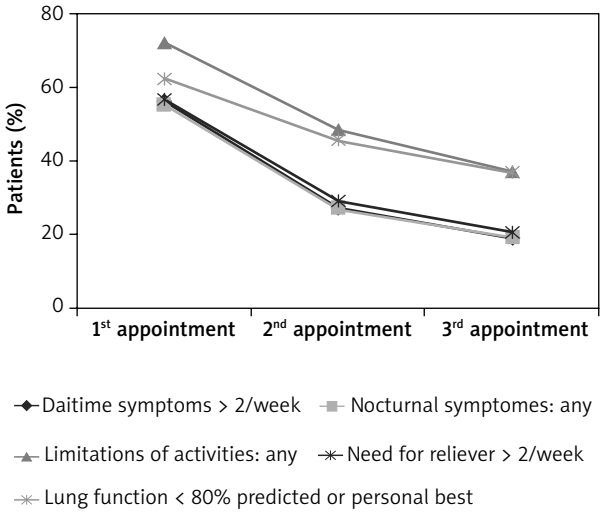

Figure 3. Changes in asthma control. After changing the treatment to the treatment recommended by GINA, patients less frequently reported symptoms of uncontrolled asthma. During the first visit at the doctor's surgery at least 54.6% of patients had uncontrolled asthma, at the last appointment at most 20.9% of patients suffer from uncontrolled asthma (Table 5)

Smoking

56.7% of the patients declared to be non-smokers, 24.7% admitted to smoke tobacco and 18.6% were passive smokers.

Physical activity

In the study group, 32.5% of the patients claimed to undertake regular physical activity, 67.5% did not exercise systematically.

Peak expiratory flow (PEF)

The average ± SD result of the PEF values in the participants was around 360 ±139 l/min. The dominant group included patients who have PEF = 400 l/min.

60–80% of the expected or proper value of PEF was observed in 50.6% of the patients, in 26.5% PEF was < 60% of proper or expected value and in 22.9% of the study population PEF was > 80% of proper or expected value. After the treatment was changed the number of patients that suffer from severe and moderate exacerbations decrease, the number of patients with light exacerbation increased.

Current state and improvement of asthma control

The analysis shows that in 56.6% of the patients daily symptoms occurred more than twice a week (> 2 t/week), and 54.6% of them suffered from nocturnal symptoms. Seventy-two percent of the participants declared certain activity limitations, 56.7% required immediate treatment > 2 t/week and 62.1% had pulmonary function lower than 80% of the normal or maximal value. After introducing treatment consistent with the current guidelines (GINA – Global Initiative For Asthma 2012), the numbers of patients that suffer from those symptoms declined (Figure 3, Table 5).

Treatment among study group

In the study group 87.9% of the patients received earlier treatment, whereas 12.1% did not undergo any therapy. The most commonly used medications were iGCs (80.0%), 54.8% of patients used long-acting β2-mimetics (LABA) and 62% short-acting β2-mimetics (SABA). 40.2% of the patients that used iGCs took budesonide, 79.7% of the participants that used SABA took salbutamol, 93.7% of LABA users took formoterol. The basic treatment that helps control asthma at the first appointment had been changed into iGCs + salmeterol (recommended by GINA guidelines). Additional drugs were prescribed according to the patients' needs and the disease requirements. Table 6 presents particular drugs that were used by the participants prior to the study and after the treatment was changed.

Adverse events (AEs) of iGCs

Adverse events were identified on the basis of the safety data sheets of drugs used. 87.1% of patients were aware of the occurrence of AEs triggered by iGCs and 71.8% were not afraid of their occurrence. 27.6% of the patients observed AEs of steroid therapy, 54.1% of them developed an infection of the mouth or airways, 36.8% suffered from dysphonia and 33.7% reported cough and bronchospasm after inhalation. Other symptoms included headaches, nausea or bruising. The details about AE occurrence are presented in Table 7.

Adverse events of β2-mimetics

Tachycardia occurred in 42.2% of the patients, 39.2% felt palpitations, 35% suffered from skeletal muscle tremor. Among the other AEs mentioned by the patients

Table 5. Asthma control among three appointments

Appointment	Daytime symptoms > 2/week	Any nocturnal symptoms	Any limitations of activities	Need for reliever > 2/week	Lung function < 80% predicted or personal best
1st	56.6%	54.6%	72.0%	56.7%	62.1%
2nd	27.4%	27.0%	48.3%	29.3%	45.6%
3rd	18.6%	19.7%	36.8%	20.9%	37.1%

Table 6. Drugs taken by patients

Group of drugs	Treatment prior to the study			Recommended treatment % of participants
	% of participants	Most commonly used		
iGCs	80	Budesonide	40.2%	34.6
		Ciclesonide	24.6%	32.2
		Fluticasone	24.5%	23.4
		Beclomethasone	10.7%	9.8
Short-acting β2-mimetics	62	Salbutamol	79.7%	57.5
		Fenoterol	20.3%	
Long-acting β2-mimetics/ salmeterol	54.8	Formoterol	93.7%	0
		Salmeterol	6.3%	100
Anti-leukotrienes	30.2			38.6
Theophylline	18.9			13.5
Oral GCs	3.2			3.1
Cromones	2			0.1
Anti-IgE	1.8			2
Other drugs	2.4			2.5

iGCs – inhaled glucocorticosteroids, oral GCs – oral glucocorticosteroids, anti-IgE – anti-immunoglobulin therapy. Other drugs included inter alia ipratropium.

Table 7. Adverse events of commonly used drugs prior to the study

Adverse events of iGCs (%)		Adverse events of β2-mimetics (%)	
Airways/mouth infection	54.1	Tachycardia	42.2
Dysphonia	36.8	Feeling of palpitations	39.2
Cough and bronchospasm after inhalation	33.7	Muscle tremor	35
Weight gain	12.2	Headaches	27.6
Weakness in muscle strength	9	Increased sweating	14.9
Hypertension	7.6	Hypokalaemia	5.3
Mood disorders	6.9	Hypomagnesemia	2.6
Oedema	5.9	Hyperglycaemia	1.6
Water and electrolyte balance disruption	3.8	Lengthening of the QT distance	1.2
Peptic ulcer disease	3.7	Increase in lactic acid and plasma	0.1
Atrophic changes of mucosa membranes	3.6	Other	5.3
Thinning of the skin	2.5		
Diabetes	2.2		
Osteoporosis	2.2		
Stretch marks	1.3		
Cataract	1.2		
Glaucoma	0.4		
Other	0.8		

According to the literature taking iGCs may result in AEs occurrence with local and systemic symptoms. Most common AEs are put into safety data sheets of medicinal products; local side effects: dysphonia, oropharyngeal candidiasis, cough, and pneumonia (among COPD patients) and systemic side effects: adrenal suppression, growth suppression, bruising, osteoporosis, cataracts, glaucoma, metabolic abnormalities (glucose, insulin, triglycerides) and psychiatric disturbances [41].

were hypertension, sore throat or insomnia (Table 7). Therefore, in 54.8% of the patients β2-agonists had to be changed.

Discussion

The study shows that people aged between 56 and 65 years are those who suffer from asthma most often.

The bar chart (Figure 1) presents that the number of participants increases with age. Patients over the age of 35 years constitute more than 80% of the whole study group. Singh, Jain and Mishra showed that most cases were diagnosed in the group of individuals aged between 16 and 30 years [4]. The data of 2016 (a study performed in the USA) show that patients aged between 35 and 64 years most often suffer from asthma among the whole population including children [5].

The results of the sex distribution of the study population demonstrate that women suffer from the disease more often than men (χ^2 test, $p < 0.0001$). It was also reported in the ECAP study [3]. Studies of the clinical profile of asthma patients and epidemiological data prove that boys are affected more often than girls and women suffer from asthma more commonly than men [6, 7]. Scientists show that this possible sex predilection can be explained by the regulatory effect of testosterone. Androgens negatively regulate group 2 innate lymphoid cells ILC2 homeostasis [8].

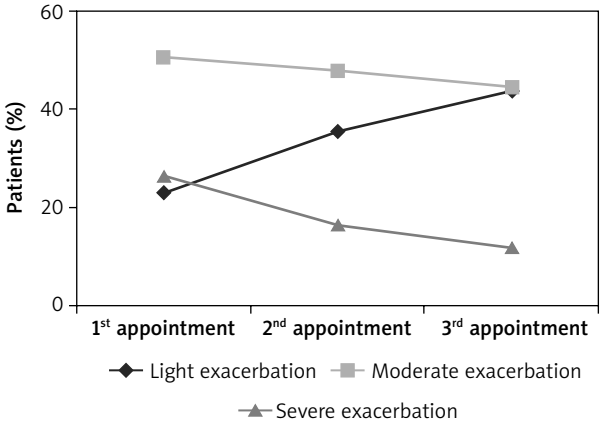

Figure 4. Severity of exacerbations among the study population. More than 25% of the study group suffer from severe exacerbations, 50.6% from moderate, and 26.5% from heavy exacerbations at the first appointment. After changing the treatment, more patients suffer from light exacerbations – almost 44%. Furthermore, fewer patients suffer from severe (26.5%–11.8%) and moderate (50.6%–44.6%) exacerbations. The measure of asthma exacerbation is the deflection of PEF in a patient suffering from its physiological value. Moderate exacerbation occurs when the PEF of a patient is from 60 to 80% of its proper value. When the PEF is higher than 80%, the exacerbation is light, when PEF is lower than 60%, the exacerbation is severe. Mean values of PEF ± SD were as follows: 1st appointment: 359.71 ±139 l/min; 2nd appointment: 389.5 ±142.07 l/min; 3rd appointment: 406.48 ±142.97 l/min

Table 8. BMI classification according to WHO

BMI [kg/m^2]	Nutritional status
Below 18.5	Underweight
18.5–24.9	Normal weight
25.0–29.9	Pre-obesity
30.0–34.9	Obesity class I
35.0–39.9	Obesity class II
Above 40	Obesity class III

The obesity level was categorized according to the WHO standards of body-mass index (BMI) (Table 8) [9]. Almost 63% of the study population suffered from overweight or obesity. Patients with overweight and obesity are at higher risk of asthma development and the disease is more difficult to control [10]. Weight reduction should be included in the treatment plan for obese patients with CBA, because even 5–10% weight loss can improve the disease control [11–13]. Schaub and Mutius showed that weight gain (within proper weight), overweight or obesity may antedate asthma onset [14]. Mechanisms that contribute to the development of asthma in obese and overweight people include changes in lung volume, induction of systemic inflammation [15].

Since asthma is not correlated with the circulatory system [16, 17], the largest group of patients had normal blood pressure and proper heart rate (80 hbs per minute) according to the classification of ESH/ESC (Table 4). Hypertension was reported in 22.4% of the patients. This score was probably a result of overweight and obesity presented in a majority of patients since these factors contribute to an increase in blood pressure and hypertension development [18].

Almost half of patients admit that they are somehow exposed to tobacco smoke. This phenomenon is very dangerous because there is strong evidence that smoking is a factor that makes asthma more difficult to control [19]. Moreover, being a passive smoker is very unhealthy because second-hand smoke has exactly the same toxins as mainstream smoke and worsens asthma attacks [20]. Excessive phlegm production and shortness of breath is more often observed in smokers than in never-smokers. Surprisingly, these parameters measured in ex-smokers are comparable to those found in never-smokers, so those changes in smokers airway epithelium are possibly reversible [21]!

More than two thirds of the participants admitted they had not taken any regular physical activity. This was probably caused by activity limitations occurring among the study population. Physical activity is a possible factor that protects against asthma development [22, 23]. Regular training sessions improve the cardio-pulmonary condition, alleviate asthma symptoms and increase the quality of life in asthmatics [22], especially high-intensity interval training [24, 25].

Peak flow meter with a questionnaire is considered as an alternative tool to spirometry for screening of asthma and chronic obstructive pulmonary disease [26]. PEF measurement shows the patency of the bronchi. The highest percentage of patients has the correct value of the PEF. Change of commonly used treatment to the standard treatment based on GINA guidelines results in less severe exacerbations (Figure 4).

Current asthma control among the study population was poor. Surprisingly, change of treatment to the standard treatment recommended by GINA has caused symptoms to occur more rarely (Figure 3). Every treatment standard and every guideline have one main goal – optimal asthma control [19]. According to the data, more than 50% of the study population had uncontrolled asthma at the beginning of the research (according to GINA definition of asthma control [27]). On the other hand, at the third appointment at most 20.9% of patients had uncontrolled asthma. Nevertheless, there are many variables contributing to asthma symptoms occurrence and its exacerbations, hence it is very challenging to put asthma under control [28].

Asthma therapies include patient and family education, environmental control, pharmacotherapy and desensitization. It is reported that the most important drugs in pharmacotherapy are iGCs in combination with LABA [29]. Among the participants involved in the PROKSAL study, the majority of the subjects received earlier treatment. In Kupryś-Lipińska study, there were 48% of adult patients that had not received drugs in the preceding year [30]! The drugs taken most often by participants of the PROKSAL study were iGCs and SABA. Panek *et al.* show that majority of patients had used iGCs and SABA [31]. In Chipps *et al.* study, SABA, iGCs and LABA were most commonly taken medications [32].

More than a quarter of the study group complain about AEs of the steroid therapy. Unfortunately, β2-mimetics also cause AEs in patients. A large number of subjects have experienced very disturbing symptoms: tachycardia and feeling palpitations. Inhaled GCs most commonly result in local AEs – oral candidiasis and dysphonia [33], but in Vitale *et al.* study at most 10% of patients complained about mouth cavity infections [34]. Del Gaudio *et al.* mentioned hoarseness and dysphonia as the main adverse event accompanying the iGCs use [35]. Suissa *et al.* reported 34% of diabetes patients among study populations using iGCs [36]. Falk *et al.* showed that the most common AEs of iGCs use were adrenal suppression, cataracts, cough and dysmenorrhea. As for LABA use, they emphasized that the most frequent AEs were angina, cataracts, cough, dysmenorrhea, dysphonia, and arrhythmia [37]. Scichilone *et al.* show that the most common AEs of LABA were tachycardia, muscle tremor, hypokalaemia and lengthening the QT distance [38]. Chotirmall *et al.* mentioned that the most common AEs of β-agonists are palpitations and tachycardia [39].

The results obtained prove that asthma is still a significant problem in Poland, there were even patients that did not receive any treatment. Moreover, despite the guidelines, Polish patients did not receive recommended treatment. A therapy which is not fully effective and additionally causes disturbing adverse events does have an impact on patients' lives and worsens asthma control. On the other hand, a proper treatment described in GINA guidelines may contribute to an effective therapy, improve asthma control and thus patients' quality of life.

The main disadvantage of this study is the limitation to a non-interventional trial, therefore, there are no data obtained from blood samples that would elevate the quality of research, for example, blood eosinophilia or IgE. Researchers did not have an opportunity to perform spirometry on all subjects due to lack of the proper equipment in each surgery.

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Conflict of interest

The authors declare no conflict of interest.

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Appendix. Questionnaire available online.

OGÓLNOPOLSKIE NIEINTERWENCYJNE BADANIE OBSERWACYJNE "PROKSAL" NR PACJENTA ☐☐☐☐☐

Profil kliniczny pacjentów rozpoczynających leczenie salmeterolem w przewlekłej astmie oskrzelowej w skojarzeniu z wziewnym glikokortykosteroidem

WIZYTA 1.

WIEK ☐☐ PŁEĆ K/M WZROST ☐☐ MASA CIAŁA ☐☐ kg CIŚNIENIE TĘTNICZE ☐☐☐/☐☐

CZĘSTOŚĆ AKCJI SERCA ☐☐☐ PALENIE TYTONIU ☐ TAK ☐ NIE ☐ BIERNE

REGULARNY WYSIŁEK FIZYCZNY ☐ TAK ☐ NIE

ASTMA ROK ROZPOZNANIA ASTMY OSKRZELOWEJ ☐☐☐☐

OCENA CIĘŻKOŚCI PRZEBIEGU ASTMY SPORADYCZNA ☐ PRZEWLEKŁA LEKKA ☐ PRZEWLEKŁA UMIARKOWANA ☐ PRZEWLEKŁA CIĘŻKA ☐

AKTUALNY PEF ☐☐☐l/min ☐☐% WARTOŚCI NALEŻNEJ

AKTUALNY STOPIEŃ KONTROLI ASTMY Objawy dzienne ☐ ≤ 2/TYDZ. ☐ > 2/TYDZ.

Objawy nocne ☐ NIE WYSTĘPUJĄ ☐ JAKIEKOLWIEK

Ograniczenia aktywności ☐ NIE WYSTĘPUJĄ ☐ JAKIEKOLWIEK

Potrzeba leczenia doraźnego ☐ ≤ 2/TYDZ. ☐ > 2/TYDZ.

Czynność płuc ☐ prawidłowa ☐ < 80% wartości należnej lub maksymalnej

LECZENIE

DOTYCHCZASOWE LECZENIE
□ Wziewny GKS PREPARAT:..... DAWKA:.....
□ Doustny GKS
□ Lek antyleukotrienowy
□ Teofilina
□ Kromony
□ Anty-IgE
□ Inny lek. Jaki?.....
□ β2-mimetyk krótko działający, Jaki?.....
□ β2-mimetyk długo działający, Jaki?.....

Powód zmiany β2-mimetyka
□ Tachykardia
□ Zwiększona potliwość
□ Hipermagnezemia
□ Wzrost stężenia kwasu mlekowego w osoczu
□ Wydłużenie odcinka QT
□ Uczucie kołatania serca
□ Drżenie mięśni szkieletowych
□ Hipokaliemia
□ Bóle głowy
□ Hiperglikemia

Zalecone leczenie
□ Wziewny GKS PREPARAT: ..... DAWKA: .....
□ Doustny GKS
□ Lek antyleukotrienowy
□ Teofilina
□ Kromony
□ Anty-IgE
□ Inny lek. Jaki?.....
□ β2-mimetyk krótko działający. Jaki?.....
□ β2-mimetyk długo działający.
□ Salmeterol

Czy zalecono suplement diety w ramach profilaktyki działań niepożądanych wGKS?
□ Tak □ Nie

Działania niepożądane wGKS
Czy pacjent jest świadomy działań niepożądanych wGKS
□ Tak □ Nie

Czy z pacjentem kiedykolwiek przeprowadzano rozmowę edukacyjną na temat działań niepożądanych wGKS?
□ Tak □ Nie

Czy pacjent kiedykolwiek zgłaszał działania niepożądane wGKS?
□ Tak □ Nie

Działania niepożądane wGKs, które wystąpiły u pacjenta od początku leczenia
□ Zakażenia jamy ustnej lub dróg oddechowych
□ Kaszel i skurcz oskrzeli po inhalacji
□ Osteoporoza
□ Nadciśnienie tętnicze
□ Jaskra
□ Choroba wrzodowa
□ Obrzęki
□ Cukrzyca
□ Ścieńczenie skóry
□ Dysfonia
□ Zmiany zanikowe błon śluzowych
□ Zaburzenia nastroju
□ Zaćma
□ Otyłość

□ Zaburzenia gospodarki wodno-elektrolitowej
□ Zwiększenie masy ciała
□ Osłabienie siły mięśniowej
□ Rozstępy
□ Inne. Jakie?.....

Czy pacjent kiedykolwiek samodzielnie zgłaszał obawę lub zaniepokojenie możliwością wystąpienia działań niepożądanych po wGKS? □ Tak □ Nie
□ Zakażenia jamy ustnej lub dróg oddechowych
□ Kaszel i skurcz oskrzeli po inhalacji
□ Osteoporoza
□ Nadciśnienie tętnicze
□ Jaskra
□ Choroba wrzodowa
□ Obrzęki
□ Cukrzyca
□ Ścieńczenie skóry
□ Dysfonia
□ Zmiany zanikowe błon śluzowych
□ Zaburzenia nastroju
□ Zaćma
□ Otyłość
□ Zaburzenia gospodarki wodno-elektrolitowej
□ Zwiększenie masy ciała
□ Osłabienie siły mięśniowej
□ Rozstępy
□ Inne. Jakie?.....

Oświadczam, że osobiście na podstawie rozmowy z pacjentem wypełniłam (wypełniłem) kwestionariusz. Fakt wypełnienia kwestionariusza nie może wpłynąć na rodzaj zastosowanej terapii.

podpis i pieczątka lekarza

OGÓLNOPOLSKIE NIEINTERWENCYJNE BADANIE OBSERWACYJNE "PROKSAL" **NR PACJENTA ☐☐☐☐☐**
Profil kliniczny pacjentów rozpoczynających leczenie salmeterolem w przewlekłej astmie oskrzelowej w skojarzeniu z wziewnym glikokortykosteroidem

WIZYTA 2. po 6 tygodniach

CIŚNIENIE TĘTNICZE ☐☐☐/☐☐ CZĘSTOŚĆ AKCJI SERCA ☐☐☐/min

AKTUALNY PEF ☐☐☐ L/MIN ☐☐% WARTOŚCI NALEŻNEJ

AKTUALNY STOPIEŃ KONTROLI ASTMY Objawy dzienne ☐ ≤ 2/TYDZ. ☐ > 2/TYDZ.

Objawy nocne ☐ NIE WYSTĘPUJĄ ☐ JAKIEKOLWIEK

Ograniczenia aktywności ☐ NIE WYSTĘPUJĄ ☐ JAKIEKOLWIEK

Potrzeba leczenia doraźnego ☐ ≤ 2/TYDZ. ☐ > 2/TYDZ.

Czynność płuc ☐ prawidłowa ☐ < 80% wartości należnej lub maksymalnej

Czy pacjent przestrzegał zaleconej terapii?
□ Tak □ Nie □ Trudno powiedzieć
Zalecone leczenie
□ Wziewny GKS PREPARAT: ..... DAWKA: .....
□ Doustny GKS
□ Lek antyleukotrienowy
□ Teofilina
□ Kromony
□ Anty-IgE
□ Inny lek. Jaki?.....
□ β2-mimetyk krótko działający. Jaki?.....
□ β2-mimetyk długo działający
□ Salmeterol

Czy zalecono suplement diety w ramach profilaktyki działań niepożądanych wGKS?
□ Tak □ Nie -->

W jaki sposób zabezpieczono pacjenta przed działaniami niepożądanymi?.....

Czy pacjent zgłaszał działania niepożądane wGKS?
□ Tak □ Nie

Działania niepożądane wGKS, które wystąpiły u pacjenta od ostatniej wizyty
□ Zakażenia jamy ustnej lub dróg oddechowych
□ Kaszel i skurcz oskrzeli po inhalacji
□ Osteoporoza
□ Nadciśnienie tętnicze
□ Jaskra
□ Choroba wrzodowa
□ Obrzęki
□ Cukrzyca
□ Ścieńczenie skóry
□ Dysfonia
□ Zmiany zanikowe błon śluzowych
□ Zaburzenia nastroju
□ Zaćma
□ Otyłość
□ Zaburzenia gospodarki wodno-elektrolitowej
□ Zwiększenie masy ciała
□ Osłabienie siły mięśniowej
□ Rozstępy
□ Inne. Jakie?.....

Czy pacjent zgłaszał działania niepożądane β2-mimetyka?
□ Tak □ Nie

Działania niepożądane β2-mimetyka, które wystąpiły u pacjenta od ostatniej wizyty
□ Tachykardia
□ Zwiększona potliwość
□ Hipermagnezemia
□ Wzrost stężenia kwasu mlekowego w osoczu
□ Wydłużenie odcinka QT
□ Uczucie kołatania serca
□ Drżenie mięśni szkieletowych
□ Hipokaliemia
□ Bóle głowy
□ Hiperglikemia

Oświadczam, że osobiście na podstawie rozmowy z pacjentem wypełniłam (wypełniłem) kwestionariusz. Fakt wypełnienia kwestionariusza nie może wpłynąć na rodzaj zastosowanej terapii.

podpis i pieczątka lekarza

OGÓLNOPOLSKIE NIEINTERWENCYJNE BADANIE OBSERWACYJNE "PROKSAL" **NR PACJENTA ☐☐☐☐☐**
Profil kliniczny pacjentów rozpoczynających leczenie salmeterolem w przewlekłej astmie oskrzelowej w skojarzeniu z wziewnym glikokortykosteroidem

WIZYTA 3. po 3 miesiącach

CIŚNIENIE TĘTNICZE ☐☐☐/☐☐ CZĘSTOŚĆ AKCJI SERCA ☐☐☐/min

AKTUALNY PEF ☐☐☐l/min ☐☐% WARTOŚCI NALEŻNEJ

AKTUALNY STOPIEŃ KONTROLI ASTMY Objawy dzienne ☐ ≤ 2/TYDZ. ☐ > 2/TYDZ.

Objawy nocne ☐ NIE WYSTĘPUJĄ ☐ JAKIEKOLWIEK

Ograniczenia aktywności ☐ NIE WYSTĘPUJĄ ☐ JAKIEKOLWIEK

Potrzeba leczenia doraźnego ☐ ≤ 2/TYDZ. ☐ > 2/TYDZ.

Czynność płuc ☐ prawidłowa ☐ < 80% wartości należnej lub maksymalnej

Czy pacjent przestrzegał zaleconej terapii?
□ Tak □ Nie □ Trudno powiedzieć

Zalecone leczenie
□ Wziewny GKS PREPARAT: ..... DAWKA: .....
□ Doustny GKS
□ Lek antyleukotrienowy
□ Teofilina
□ Kromony
□ Anty-IgE
□ Inny lek. Jaki?.....
□ β2-mimetyk krótko działający. Jaki?.....
□ β2-mimetyk długo działający
□ Salmeterol

Czy zalecono suplement diety w ramach profilaktyki działań niepożądanych wGKS?
□ Tak □ Nie

W jaki sposób zabezpieczono pacjenta przed działaniami niepożądanymi?.....

Czy pacjent zgłaszał działania niepożądane wGKS?
□ Tak □ Nie

Działania niepożądane wGKS, które wystąpiły u pacjenta od ostatniej wizyty
□ Zakażenia jamy ustnej lub dróg oddechowych
□ Kaszel i skurcz oskrzeli po inhalacji
□ Osteoporoza
□ Nadciśnienie tętnicze
□ Jaskra
□ Choroba wrzodowa
□ Obrzęki
□ Cukrzyca
□ Ścieńczenie skóry
□ Dysfonia
□ Zmiany zanikowe błon śluzowych
□ Zaburzenia nastroju
□ Zaćma
□ Otyłość
□ Zaburzenia gospodarki wodno-elektrolitowej
□ Zwiększenie masy ciała
□ Osłabienie siły mięśniowej
□ Rozstępy
□ Inne. Jakie?.....

Czy pacjent zgłaszał działania niepożądane β2-mimetyka?
□ Tak □ Nie

Działania niepożądane β2-mimetyka, które wystąpiły u pacjenta od ostatniej wizyty
□ Tachykardia
□ Zwiększona potliwość
□ Hipermagnezemia
□ Wzrost stężenia kwasu mlekowego w osoczu
□ Wydłużenie odcinka QT
□ Uczucie kołatania serca
□ Drżenie mięśni szkieletowych
□ Hipokaliemia
□ Bóle głowy
□ Hiperglikemia

Oświadczam, że osobiście na podstawie rozmowy z pacjentem wypełniłam (wypełniłem) kwestionariusz. Fakt wypełnienia kwestionariusza nie może wpłynąć na rodzaj zastosowanej terapii.

podpis i pieczątka lekarza