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Outpatients specialist care of chronic obstructive pulmonary disease patients in Poland — results of the KOMPAS study

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Abstract

Introduction: COPD is one of the most important lung diseases. It is responsible for significant proportion of outpatients pulmonary clinics visits. Data on outpatients care of COPD patients in Poland are limited. This article presents design of the KOMPAS study and basic results relating to COPD patients.

Material and methods: The aim of this prospective study was to describe population of patients with COPD treated by specialists, and to characterize methods of care used in various COPD stages. Participating physicians used pocket PCs equipped with specially developed software to collect COPD patients' data.

Results: Data on 2958 COPD patients were analyzed. 2/3 of patients were males. Mean patients age was 63 years and mean FEV₁ — 57% of predicted value. 86% of all subjects underwent spirometry during the first visit or the previous 6 months. Cough and exertional dyspnoea were the most frequently reported COPD symptoms (about 80% of patients). At the first visit 32% of subjects were current smokers and 51% were ex-smokers. 17% of all study patients have never smoked. Before inclusion 2/3 of patients were treated with bronchodilator, and about 1/3 with inhaled steroid. After entering the study, over 90% received bronchodilator and more than 2/3 received inhaled steroid. Differences in treatment between stages of COPD based on its severity were relatively small.

Conclusions: results of the KOMPAS study provide basic information about COPD outpatients care in Poland. These data, especially concerning physicians' compliance with current COPD guidelines, may be useful in planning undergraduate/postgraduate training for physicians and for those who are responsible for health resource allocation.

Key words: chronic obstructive pulmonary disease, outpatients care, KOMPAS study

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Introduction

Chronic obstructive pulmonary disease is one of the most common chronic respiratory diseases. Among individuals over 40 years of age, it constitutes one of the most important causes of morbidity

and mortality [1, 2]. Prevalence of COPD is estimated to be at least 5% of general population, but because the disease affects mainly elderly people, in the adult population its prevalence exceeds 10% [3]. According to the latest studies led by the *Burden of Obstructive Lung Disease* (BOLD) Initiative,

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COPD prevalence in the population aged at least 40 years in Poland [4] as well as worldwide [5] can exceed 20%. These patients often need intensive medical care, and their treatment is expensive [6]. COPD is a reason for substantial proportion of all outpatient visits caused by lung diseases. The prevalence of COPD is expected to grow in the upcoming years, placing more burden on the health care systems [7].

Standards of care for COPD patients are set by widely accepted guidelines, especially *Global Initiative for Chronic Obstructive Lung Disease* (GOLD) guidelines [8]. In Poland such guidelines have been developed by the Polish Society of Lung Diseases [9]. Effective implementation of guidelines is important to improve of the quality of care [10]. Only few studies aiming to describe COPD outpatient population in Poland are available. Lack of data concerning COPD and the lack of social awareness of this disease is illustrated by the fact, that the last Polish Main Statistical Office (GUS) Report on Polish citizens state of health does not even mention COPD [11]. The study published in 2004, based on data collected from patients, has demonstrated that COPD management (especially in stable COPD) is often incompatible with published guidelines (however, these data were based on analyses of only 105 cases) [12]. Optimistic results concerning quality of care of COPD patients were brought by the study based on the results of questionnaire among pulmonary physicians [13]. However, quality of this study is reduced by the response rate of only 10%. In other European countries, care of COPD patients is often at variance with guidelines, especially in primary care settings [14–16]. In Poland, patients care is provided largely by specialists — in 2005, 34% of all outpatient visits were performed by specialists [17]. In our country, specialists often take care not only of the most severe cases, but also patients with mild and moderate disease.

This article is the first of planned publications presenting the results of the KOMPAS project. It describes methodology of the KOMPAS study and its main results concerning COPD subjects.

The main aim of the study was to describe the population of patients diagnosed with COPD, cared by pulmonologists and allergologists, and to characterize the management in individual COPD stages.

Material and methods

Six hundred non-randomly chosen physicians from all main administrative parts of Poland (mostly pulmonologists, allergologists and pediatri-

cians, treating COPD and asthma patients) were invited to participate in the study. In order to become the study investigator, each physician had to include at least 10 subjects and continue their observation for at least 12 months and 4 visits.

The KOMPAS study included COPD and asthma patients treated in outpatient clinics, however this article focuses only on COPD patients. Data on asthma patients will be presented in a separate publication.

Physicians participating in the study were provided with pocket PCs (Dell Axim X30, Dell, Poland), pre-loaded with software exclusively developed for this study, including electronic questionnaire automatically saving patient information. The questionnaire comprised questions on COPD severity stage, the presence of cough, the presence and intensity of exertional and nocturnal dyspnoea, the presence of right-heart failure (typical signs and symptoms, as judged by physicians), burden of the disease as judged by the patients, spirometry results, information about tobacco smoking habit and physician's satisfaction of treatment results. COPD diagnosis and assignment of severity stage were based on a judgment of clinicians participating in the study. Written instructions for physicians suggested using GOLD guidelines classification of severity, based on post-bronchodilator spirometry results (Stage 1: $FEV_1/FVC < 0.7$ and $FEV_1 \geq 80\%$ pred.; Stage 2: $FEV_1/FVC < 0.7$ and $FEV_1 \geq 50\%$ and $< 80\%$ pred.; Stage 3: $FEV_1/FVC < 0.7$ and $FEV_1 \geq 30\%$ and $< 50\%$ pred.; Stage 4: $FEV_1/FVC < 0.7$ and $FEV_1 < 30\%$ or $FEV_1 < 50\%$ and chronic respiratory insufficiency) [8]. Because during project-phase of the study GOLD guidelines also included COPD Stage 0 — at risk (subjects which do not have COPD), some healthy subjects in previous GOLD 0 Stage were included. COPD exacerbations were diagnosed based on physicians' judgment. Symptoms intensity was quantified in 7-steps scale, where steps 1 to 7 referred to growing intensity of symptoms (for example for question concerning relief use of bronchodilators: 1 — never, 2 — ≤ 1 /month, 3 — > 1 /months but < 1 /week, 4 — on average 1/week, 5 — > 1 /week but < 1 /day, 6 — every day, 7 — few times a day). The questionnaire also comprised information about current treatment and its changes. Data on treatment before inclusion (based on information collected at inclusion, during the 1st visit) were only collected for subjects who previously have not been treated by the physicians participating in the study.

Data entered by physicians were saved on the memory cards, which were subsequently transferred to the study data coordinating center. Data were

saved and kept in a way preventing identification of patients — only patient's code was entered and the data from data memory card could have been read only with individual Pocket PC of the physician who took care of the patient, or in the study data coordinating center.

Results are presented as a mean (numerical variables) or as a percentage (categorical variables). Between group differences were analyzed using student's T test, U Mann-Whitey's test, χ^2 test and Kruskal-Wallis test.

The study has been financed by a research grant from AstraZeneca. Sponsor has chosen physicians participating in the study but had no influence of any other kind on study planning, data analyzes or publication content.

Results

Characteristics of the physicians

These data apply to all participating physicians. Data from 428 physicians were obtained; women constituted 57.7%, men — 41.1% (1.2% researchers did not provide information about their gender). 47% physicians have had the experience of working longer than 10 years, whereas 38.6% — longer than 20 years. 45% have had only one workplace; others worked in at least two workplaces. Proportion of specialists in different disciplines is depicted on Table 1. Alergologists have almost exclusively included into the study patients with asthma (94% of their patients), whereas 46% patients cared by pulmonologists have had COPD.

Characteristics of the patients

A total of 13 545 patients were enrolled into the study. COPD have been diagnosed in 3315 patients (24.5% of all subjects). About 2% of all study cases were removed from further analyses due to unacceptable data quality. Also patients with COPD included by pediatricians were removed

Table 1. Specialty of the doctors participating in the study

Specialty	Proportion of physicians (%)
Pulmonology	40.7
Allergology	15.9
Allergology and pulmonology	0.9
Pediatrics	10.0
Pediatrics and pulmonology	10.3
Pediatrics and allergology	10.7
Pediatrics. pulmonology and allergology	6.6
No data available	4.9

from analyses (9% of COPD subjects). The results presented here are based on analyses of the remaining 2958 patients.

68.5% of COPD subjects were previously treated by physicians participating in the study, whereas 31.5% patients were consulted by study physicians for the first time at the enrollment to the study. Main characteristics of patients are presented in Table 2. Figure 1 depicts proportion of different severity stages during the first study visit. Men were significantly older, had worse lung function (Table 2) and more severe COPD. During the next visits proportions of COPD severity stages were similar. Mean patients' age was 62.9 years; patients were significantly older in consecutive COPD stages. During the first visit (or up to 6 month before) spirometry has been performed in 86% COPD subjects; proportion of patients with various numbers of spirometry results during the first 5 visits is depicted in Figure 2. FEV₁ measured during the first visit was significantly smaller in patients with more severe COPD stages and with progression of time since COPD diagnosis. In 29% subjects FEV₁/FVC was ≥ 0.7 . In this group, the proportion of women was significantly greater than in other subjects (38% vs. 24%); they were signifi-

Table 2. Basic characteristics of COPD patients

	Men (n = 2251)	Women (n = 999)	Total (n = 3250)	p for difference between sexes
Sex	69.3%	30.7%	—	—
Age (years)	63.4 (SD \pm 10.2)	61.7 (SD \pm 10.3)	62.9 (SD \pm 10.3)	< 0.0000*
FEV ₁ (% predicted)	55.7 (SD \pm 16.9)	61.3 (SD \pm 17.4)	57.4 (SD \pm 17.2)	< 0.0000*
FEV ₁ /FVC (%)	64.3 (SD \pm 15.0)	68.9 (SD \pm 15.4)	65.7 (SD \pm 15.3)	< 0.0000*
Subjects cared by study doctor before inclusion	69.2%	66.6%	68.4%	0.13**

*U Mann-Whitney's test; ** χ^2 test; FEV₁ — forced expiratory volume; FVC — forced vital capacity; SD — standard deviation

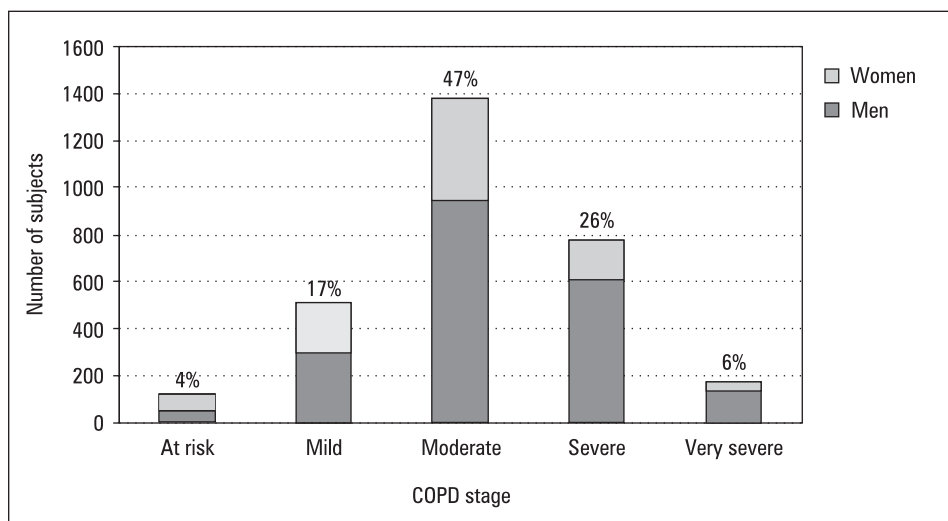


Figure 1. Proportion of COPD subjects in relation to COPD Stages (during first visit)

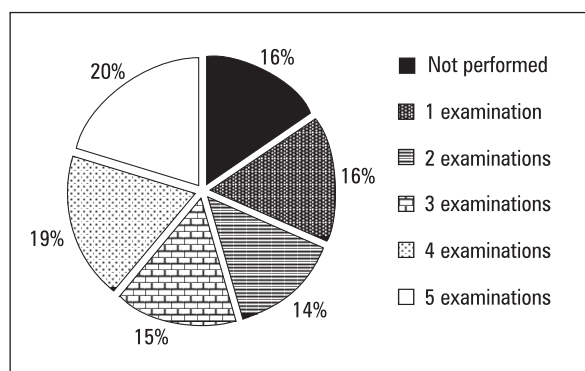


Figure 2. Frequency of spirometry during the first 5 visits in the study

cantly younger, had larger mean FEV₁ and smaller proportion were smokers. Subjects with FEV₁/FVC ≥ 0.7 were less likely to have night and exertional dyspnoea, but the proportion of subjects with cough was similar as in subjects with FEV₁/FVC < 0.7. On consecutive visits, gradual improvement of FEV₁ has been seen (in comparison to value at the first visit); this improvement was much more pronounced in subjects with exacerbation at first visit (Fig. 3). FEV₁ improvement was larger in subjects with initial FEV₁/FVC < 0.7.

Most COPD patients have complained about cough (83%) and exertional dyspnoea (78%). About half of all study subjects have had nocturnal dyspnoea attacks, whereas symptoms of right heart failure were present in 15%. The proportions of subjects complaining about cough were not significantly different between COPD stages (Fig. 4). On the contrary, percentage of subjects with nocturnal and exertional dyspnoea has been increasing with disease severity. Symptoms of right heart

failure were present mainly in severe and very severe COPD. The severity of symptoms, as well as consumption of rescue drugs (both assessed in 7. step scale) increased with growing COPD severity. Current smokers (as compared to ex- and never-smokers) more often presented with cough and night dyspnoea and their disease was more troublesome (as judged by the patients). Burden of COPD symptoms was more pronounced in patients, who were not cared by the study physicians before inclusion.

At the first study visit, 19% of patients presented with COPD exacerbation and another 11% have had exacerbation since the previous medical visit. As the severity of COPD increased, larger proportion of patients presented with exacerbation on the first visit (Fig. 5). Proportion of exacerbations did not differ significantly between patients with FEV₁/FVC < 0.7 and those with FEV₁/FVC ≥ 0.7. During consecutive visits proportion of patients with COPD exacerbations was lower (Fig. 6).

During entry into the KOMPAS Study, 32% COPD patients were current smokers, 51% were ex-smokers and remaining 17% have never smoked. (Fig. 7). Among women proportion of never-smokers was 33%, whereas in men — 10%. Proportion of smokers has significantly decreased during consecutive visits, however this observation needs further analyses.

Mean age, gender, severity stages distribution and proportion of subjects who had spirometry performed were not significantly different between subjects cared by allergologists (n = 163) and pulmonologists (n = 2487). Proportion of subjects with FEV₁/FVC > 0.7 was significantly larger in subjects cared by allergologists (53% vs. 25%).

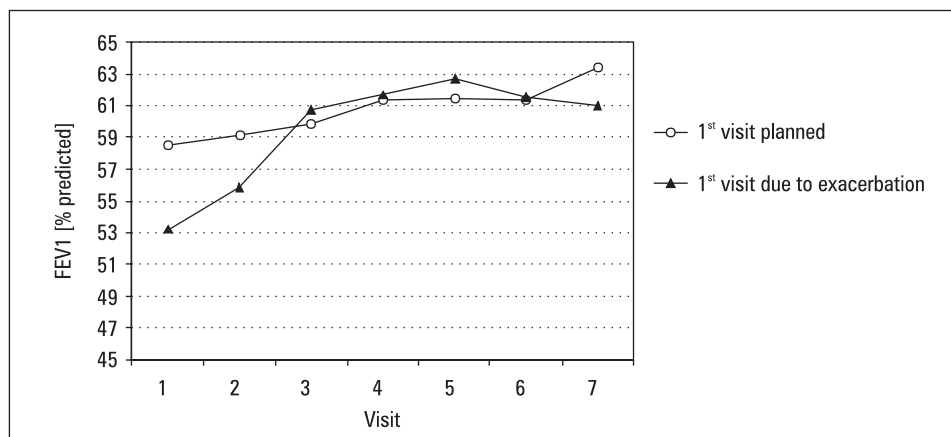


Figure 3. Average FEV₁ values during consecutive visits (all patients)

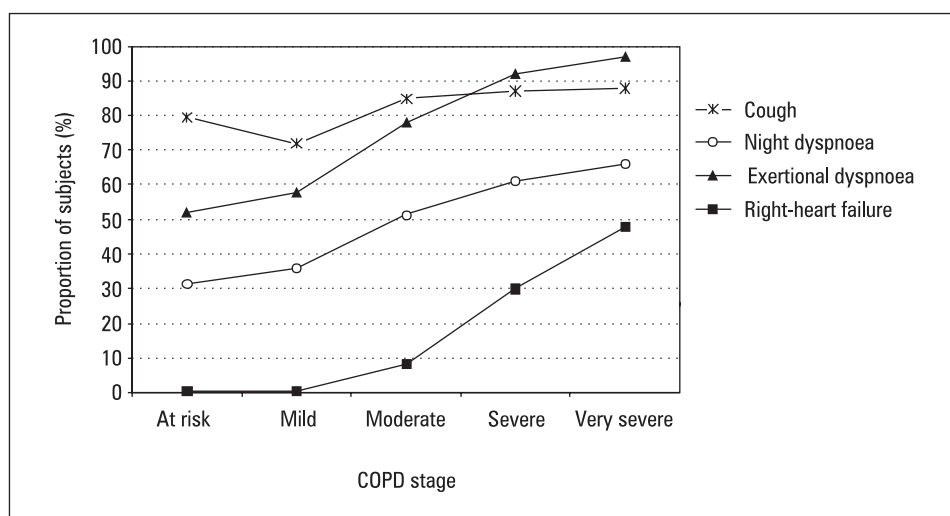


Figure 4. Prevalence of COPD signs and symptoms in relation to disease stage

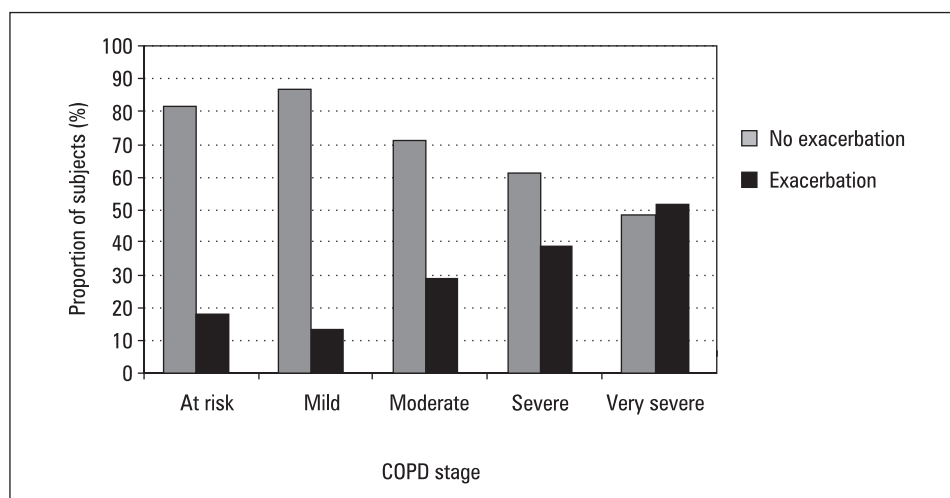


Figure 5. Prevalence of exacerbations during 1st visit among patients in relation to COPD stage

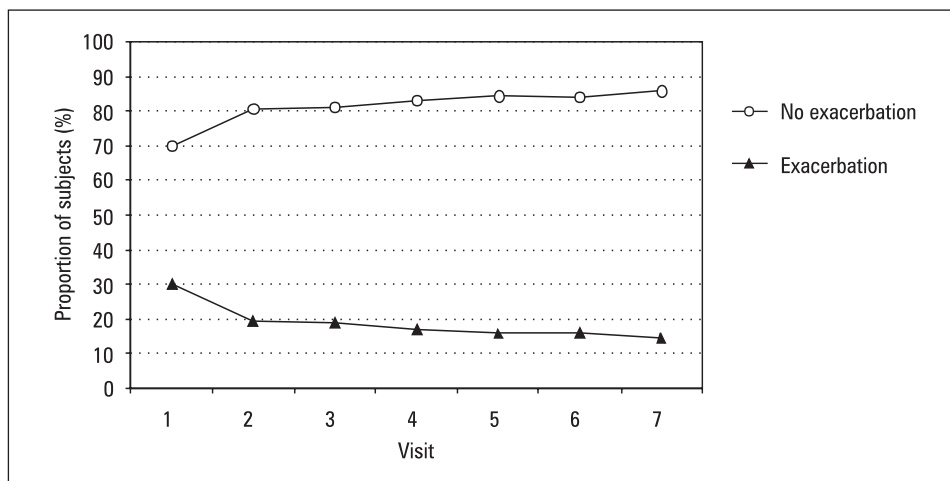


Figure 6. Prevalence of exacerbations during consecutive visits among all patients

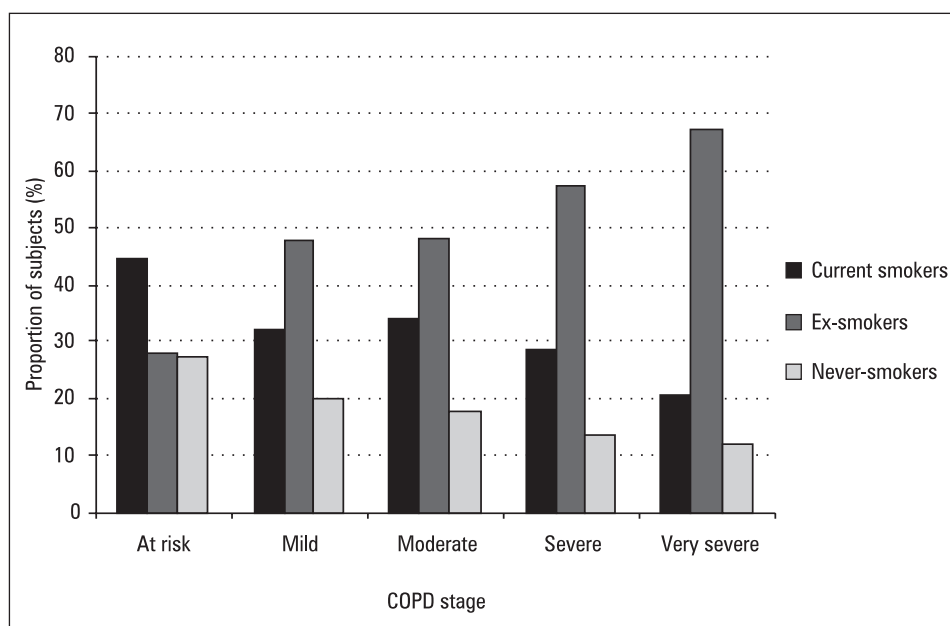


Figure 7. Prevalence of tobacco smoking in COPD patients (data from 1st visit)

Treatment

Before entry into the study about 2/3 of all patients have received any bronchodilator, and more than a 1/3 — inhaled steroid. Data on pharmacotherapy used by the patients before entry are presented in Table 3. Data on treatment prescribed during the 1st visit (after inclusion) are presented in Table 4. After inclusion, the study patients were treated more intensively, and more differences in treatment were present among COPD stages than before inclusion. More than 90% of all study subjects have received long acting bronchodilator and about 70% — inhaled steroid. There were no significant differences in treatment between subjects with z $FEV_1/FVC < 0.7$ and those with $FEV_1/$

$FVC \geq 0.7$. Inhaled steroids were used in large proportion of mild COPD subjects, as well as in those in stage 0 (“at risk”). Allergologists and pulmonologists used bronchodilators in similar proportion of subjects, whereas significantly more patients treated by allergologists have received inhaled steroids (86% vs. 68%).

Discussion

This article is the first publication of the upcoming series, presenting results of the KOMPAS Study (Complex Observational Study of COPD and Asthma Patients). The study involved physicians

Table 3. Treatment in individual COPD stages before inclusion into the study. Table data apply only to patients who were not treated by study doctors before study inclusion (n = 1027). Results presented as a proportion of all subjects who received a drug from given class

COPD stage	SABA	LABA	Short acting anticholinergics	Long acting anticholinergics	Inhaled CS	Oral CS	Methyloxanthines	Expectorants
At risk	10	43.3	5	0	33.3	1.7	20	11.7
Mild	15	48.5	18	0	36.5	1	18.5	9
Moderate	27.3	49.7	15.5	0	33.4	2.9	30.5	12.6
Severe	34.9	54.9	19.1	0.4	43.4	1.7	48.1	16.6
Very severe	41.5	65.9	43.9	0	46.3	9.8	61	14.6
All subjects	26.2	50.9	17.3	0.1	36.8	2.4	32.8	12.9

CS — corticosteroids; LABA — long acting β_2 -agonists; SABA — short acting β_2 -agonists

Table 4. Treatment in individual COPD stages after 1st visit (all patients, n = 3250). Results presented as a proportion of all subjects who received a drug from given class

COPD stage	SABA	LABA	Short acting anticholinergics	Long acting anticholinergics	Inhaled CS	Oral CS	Methyloxanthines	Expectorants
At risk	27.0	67.9	33.6	0	46.7	0	21.2	17.5
Mild	24.6	84.8	38.0	0.4	62.2	0.5	26.9	20.7
Moderate	41.2	89.7	47.6	0.7	70.2	4.8	52.9	33.3
Severe	54.9	90.5	53.7	1.6	83.9	14.1	71.1	34.9
Very severe	70.5	92.1	55.3	5.3	79.5	26.8	76.3	43.2
All subjects	43.0	88.3	47.4	1.1	71.9	7.6	53.1	31.4

CS — corticosteroids; LABA — long acting β_2 -agonists; SABA — short acting β_2 -agonists

from all regions of Poland, most of them specialists with long work experience. Results cannot be treated as fully representative, however, because the study has included non-randomly selected clinicians. Nevertheless, it included about 20% of Polish pulmonologists [17] as well as large proportion of allergologists and pediatricians, and thus, it provides an important information about outpatients pulmonary specialist care in Poland.

COPD subjects were predominantly male. Analyzing the proportions of COPD severity stages one has to remember, that these results are based mostly on patients referred to specialists, thus the proportion of severe and very severe COPD (32%) is larger than in the general population of COPD subjects [4].

Over 80% of patients with spirometry performed during the 1st visit or up to 6 month prior, proves good access to spirometry. 20% of subjects have had spirometry performed on each of the first 5 visits. Of note, about 15% of patients did not have spirometry performed during the first 5 visits. COPD diagnosis, in these subjects, can be questioned, however, in most of them COPD has been dia-

gnosed more than one year prior to the 1st visit. COPD diagnosis was based on physician's decision; our aim was to describe population of subjects with COPD diagnosed by physicians', regardless of its relationship to current guidelines. We also wanted to assess, how often spirometry was used in diagnosis of COPD and care of patients with COPD.

During the 1st visit, the proportion of smokers among COPD subjects was similar to such proportion in general population of Poland [10]. On consecutive visits percentage of smokers among studied subjects has been declining gradually. Our results, similarly to many recent papers on COPD [4, 18], demonstrate that substantial proportion of COPD subjects has never smoked tobacco. Similarly to other studies women were more prevalent in never-smokers COPD patients.

Substantial proportion of COPD subjects has not fulfilled spirometric COPD criteria ($FEV_1/FVC < 0.7$). To some extent it is caused by inclusion into the study subjects in stage 0 (stage 0 was present in the GOLD Guidelines at the time of study design). However, among subjects in other COPD stages proportion of those with $FEV_1/FVC > 0.7$ is

substantial which demonstrates discrepancy between physicians' diagnosis and current diagnostic criteria in those subjects. It is probable, that some of the study subjects, especially those cared by allergologists (among those subjects proportion of those with $FEV_1/FVC > 0.7$ was significantly larger) actually have had bronchial asthma. The treatment used and its effectiveness did not differ significantly between those two groups of patients — results of the analyses of the data from consecutive visits, performed after exclusion of subjects with $FEV_1/FVC > 0.7$ were not significantly different. Proportion of subjects with $FEV_1/FVC > 0.7$ is even smaller than in some published studies [21, 22], which could have been caused by performing those studies in primary care settings.

Our results suggest that treatment by specialists involved in the study was effective — FEV_1 has been increasing and proportion of subjects with exacerbations has been declining during consecutive visits. These observations were not affected by exclusion from analyses subjects with $FEV_1/FVC > 0.7$.

Data concerning treatment before inclusion (concerning patients who had not been treated earlier by the study clinicians) demonstrate that treatment was less intensive prior to inclusion. The proportions of patients treated with bronchodilators and inhaled steroids were higher than expected, which could have been caused by selection of study population (subjects sent for consultation to specialists). Differences in the treatment intensity between COPD stages were, however, relatively small. After inclusion, the study patients were treated even more intensively, and proportion of subjects treated with different drug classes were the same as in the remaining patients (i.e. those treated by the study doctors before inclusion). Data on treatment used by the study doctors demonstrate extensive use of available drugs. Most COPD subjects have received intensive treatment. While in severe COPD such treatment is indicated and often necessary [8, 9], of note is the use of multi-drug treatment in less severe cases. Relatively large proportion of subjects were treated with methylxanthines. Inhaled glucocorticosteroids were used early in the disease course, whereas current guidelines recommend their use in severe and very severe COPD with frequent exacerbations [8]. In our study these drugs were used in most COPD stages, including subjects at risk of COPD. These data suggest a need for continuing the activities aiming at dissemination and implementation of evidence-based guidelines, accepted by Polish and international scientific societies [8, 9].

Conclusions

In conclusion, we believe that the KOMPAS study provides basic information about secondary and tertiary outpatient COPD care in Poland. Inclusion of a large group of physicians and patients constitutes to the strength of our study, allowing description of management in different COPD stages. The limitation of the study is lack of random selection of physicians and patients. Despite the fact that our study included substantial proportion of physicians of different specialties in Poland, one cannot exclude, that management methods used by study physicians were significantly different from those who did not participate. Gradual improvement in COPD symptoms and spirometry results in patients included in the study, as well as the relatively small differences in treatment used in various COPD stages are our most important observations.

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