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Research Article

Management of Chronic Obstructive Pulmonary Disease (COPD) by German Lung Specialized Practitioners: Results of a Prospective Interview Study

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Abstract

Patients with chronic obstructive pulmonary disease (COPD) show persistent respiratory symptoms and airflow limitation. COPD causes an increased morbidity as well as mortality and is associated with significant social and economic burden. This interview study with 68 lung specialized practitioners (pneumologists) was conducted to gain insight into the management of COPD in Germany to identify issues, burdens and prevalence of COPD. The results of this study reveal a high workload for pneumologists, who are treating 685 COPD patients on average per quarter. Patients with moderate airflow limitation (GOLD 2) are initially treated using long acting muscarinic antagonists (LAMA), long acting beta-2-angonists (LABA) or a LAMA/LABA combination. Nevertheless, significant proportions of patients in GOLD airway limitation severities 2, 3 and 4are frequently treated using inhaled corticosteroid (ICS) containing regimens (20.7%, 38.4% and 54.3%, respectively), although pneumologists stated that ICS use should be less frequent used based on the latest study results. One reason might be the concern that patients not only suffer from COPD but also asthma-COPD-overlap (ACO). In conclusion, our study shows a high workload for pneumologists in Germany. They are up to date with respect to latest publications and recommendations, but the concern of ACO leads to a stronger usage of ICS containing regimes than recommended by strategies and publications.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is characterized by persistent respiratory symptoms and airflow limitation due to airway or alveolar abnormalities, usually caused by significant exposure to noxious particles and gases. The main risk factor is exposure to cigarette smoke. COPD is one of the leading causes of morbidity and mortality worldwide, and is associated with a significant economic and social burden. Patients diagnosed with COPD are mainly treated using pharmacological inhalation therapies, with the choice of therapy class dependent on the severity of the patients' COPD. Pharmacological therapy is used to reduce COPD symptoms, reduce the frequency and severity of exacerbations, and improve health status and exercise tolerance. The severity of airflow limitation is classified as mild or GOLD 1 (FEV1 ≥ 80% predicted), moderate or GOLD 2 (50% ≤ FEV1 <80% predicted), severe or GOLD 3 (≤ 30% FEV1 <50% predicted) and very severe or GOLD 4 (FEV1 <30% predicted) [1].

The BOLD study investigated the prevalence of COPD in Germany in an unselected population of 683 adults with an age of 40 years or older and found it to be 13.2% [2]. Besides BOLD, data on COPD prevalence in Germany is rare and inconsistent. Nevertheless, because of an increasing exposure to risk factors (i.e. cigarette smoke, exhaust gases) it is expected that the prevalence of COPD will rise in the next 30 years [3]. In parallel with a potential rise in the number of patients with COPD, it is suspected that the management of lung disease may deteriorate due to the high and increasing workload for German lung specialist practitioners [4].

An unknown factor in the management of COPD are the preferred treatment options of lung specialized practitioners and their decision criteria for a specific treatment option. The guideline equivalent and globally recognized Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) Global Strategy for the Diagnosis, Management and Prevention of COPD provides clear recommendations for the treatment of COPD patients in different stages of disease severity [1], but it is not known if German pneumologists follow these recommendations. Furthermore, several "benchmark" clinical studies such as FLAME (Indacaterol/Glycopyrronium vs. Salmeterol/Fluticasone) [5], TORCH (Salmeterol vs. Fluticasone vs. Salmeterol/Fluticasone vs. Placebo) [6], and WISDOM (Tiotropium+Salmeterol vs. Salmeterol+Tiotropium+Fluticasone) [7], were published in the last

years. These studies had a strong impact in the scientific COPD community, but it is not known if any of these studies has had an influence on the treatment decision of pneumologists in Germany.

Besides studies, a health technology assessment (HTA), in Germany, basically called Benefit Assessment of the Gemeinsamer Bundesausschusses (G-BA) is mandatory for all new marketed products in Germany. This HTA evaluates the efficacy and safety of new treatment options compared to the standard of care in each indication based on clinical study results [8]. All COPD medications marketed after January 1st, 2011, went through this process, but to the best of our knowledge it is not known if the HTA assessments impacted the prescribing behavior of lung specialized practitioners.

The aim of our study was to investigate the prevalence and management of COPD in Germany. In particular, we wanted to identify decision criteria of pneumologists for specific COPD treatment options and what impact clinical study results and/or HTA assessments have on their prescribing decisions. We specifically focused on GOLD 2 patients, since this is the biggest group of patients in Germany receiving a COPD treatment [2]. The results of our study will help improve understanding of the management of COPD in Germany, as well as to identify issues and burden of COPD management.

METHODS

This prospective interview study was conducted with 68 lung specialized practitioners in Germany. To ensure an equal distribution of interviewed pneumologists, Germany was divided into ten regions and the final number of interviewed pneumologists was equal in percentage in each of these ten regions. Information was gathered by providing a self-completing questionnaire to the pneumologists and by face-to-face interviews. The self-completing and interview questionnaires contained questions with multiple-choice answers as well as open answers (Table 1). The questionnaires were developed with support of three lung specialized practitioners in Germany in order to (i) ensure understandability, (ii) to determine the burden of COPD to the specialized lung practitioners in Germany, and (iii) to obtain information on the pharmacological management of COPD in Germany. Face-to-face interviews were conducted by UCB sales representatives. The study period lasted from March 2016 until January 2017.

For analysis, multiple-choice answers were analyzed from raw data. Open answers were clustered into groups of similar responses (e.g. device, duration of action, studies) before analysis. The complete collected data was analyzed using descriptive and explorative methods. Mean values and standard deviations were calculated as appropriate. N-numbers of all analysis refer to the number of pneumologists answering the particular question.

RESULTS AND DISCUSSIONS

Results

Frequency of COPD in Germany: Based on our survey the 68 interviewed German lung specialists are treating an average of 684.7 (SD 481.1) COPD patients per quarter, which can be split by severity into118.1 (SD 137.8) GOLD I patients, 252.7 (SD 179.0) GOLD II patients, 192.7 (SD 164.2) GOLD III patients, and 99.0 (SD 85.1) GOLD IV patients (Table 2). In addition, study participants reported that they averagely diagnose 136.5 (SD 134.7) new COPD patients per quarter (Table 2). In general, 70.5% of all COPD patients are transferred to the lung specialists from general practitioners (GPs), with the three main transfer reasons therapy optimization (63.2%), diagnosis (58.8%), and exacerbations (35.3%). Approximately 66.7% of these COPD patients are afterwards further treated by interviewed lung specialists and not sent back to their GPs for main treatment decisions.

Overall treatment approach in patients with COPD: The survey showed increased use of combination therapy compared to monotherapy in patients with greater degrees of airway limitation. The pneumologists stated that combination therapy is prescribed to just over half (55.3%) of patients with GOLD II airway limitation, to most patients (88.3%) with GOLD III airway limitation and to nearly all patients (96.2%) with GOLD IV airway limitation (Figure 1). The percentages of pneumologists using long-acting β_2-agonists (LABA) or long-acting muscarinic antagonists (LAMA) as monotherapy were higher when treating patients with GOLD II airway limitation (25.9% and 18.8%), than for patients with GOLD III (7.5% and 4.2%, respectively) or GOLD IV airway limitation (2.6% and 1.2%, respectively), while the percentages of pneumologists using LABA/LAMA combinations, or combinations containing a LABA/LAMA and inhaled corticosteroid (ICS) were higher for patients with GOLD III airway limitation (49.9% and 22.8%, respectively) or GOLD IV airway limitation (41.6% and 42.7%, respectively), than for treating patients with GOLD II airway limitation (34.4% and 7.2%, respectively). There was no notable difference in the percentages of pneumologists prescribing combinations containing an ICS and LABA or an ICS and LAMA according to degree of airway limitation, but overall just over half of all patients with GOLD IV airway limitation were prescribed a combination treatment that included an ICS (Figure 2).

The survey focused further on the treatment of patients with GOLD II airway limitation. Most of the interviewed lung specialists (76.3%) commenced maintenance treatment of their GOLD II patients with either LAMA or LABA monotherapy (42.6% and 33.8%, respectively).Only 17.6% of lung specialists commenced maintenance treatment of GOLD II patients with a LABA/LAMA combination (Figure 2A). The main escalation therapy is the LAMA/LABA combination (67.6%), whereas 17.6% of the pneumologists gave no information on escalation therapy (Figure 2B). In addition, 67.6% of lung specialists answered that they are treating GOLD 2 patients with ICS containing regimens. Main reasons for ICS usage are the asthma-COPD-overlap-syndrome (ACO) (39.7%), frequent exacerbations (22.1%), and short-term escalation after an exacerbation (11.8%).

At interview, the three most important therapeutic objectives of the lung specialists in the treatment of their COPD patients are: reduction of dyspnea, followed by improvement of quality of life, and prevention of exacerbations. In addition, lung specialists stated that 58.7% of their COPD patients are registered for the COPD disease management program (DMP), a structured treatment program to improve care of patients with chronic

Table 1: Questionnaires: 1 to 6 self-completing questionnaire; 7 to 16 interview questionnaire.

Question	Type of answer and answers options
1. How many patients are you treating per quarter practice and how many are transferred from GPs?	Open answer with prespecified COPD severities: GOLD I, GOLD II, GOLD III, GOLD IV, total
2. How many new COPD diagnoses are you making per quarter?	Open answer with prespecified COPD severities: GOLD I, GOLD II, GOLD III, GOLD IV, total
3. What are the characteristics of patients transferred from GP to you?	Open answer
4. How many patients are transferred back to the GPs?	Open answer
5. Which long term maintenance treatment are you using for treatment of GOLD II / III / IV COPD patients and what percentage of patients are receiving each therapy	Monotherapy:_____%
	Combination therapy:_____%
	LAMA:%
	LABA: %
	LAMA+LABA:%
	ICS+LAMA:%
	ICS+LABA:%
	ICS+LAMA+LABA:_____%
6. What is your ranking for the following therapeutic objectives?	Rank 1 (most important) to 5 (minor important)
	Prevention of exacerbations:
	Reduction of dyspnea:
	Improvement of quality of life:
	Improvement of lung function:
	Reduction of rescue medication use:
7. How do you start the treatment of GOLD II patients?	Open answer
8. What is your preferred escalation therapy for GOLD II patients?	Open answer
9. Are you treating GOLD II patients with ICS? If yes, what are the reasons?	Yes/No Open answer
10. How many of your COPD patients have you registered for DMP and what are the reasons?	Open answer
11. How are you differentiating within the substance classes for maintenance COPD treatment?	Open answer with prespecified substance classes
	LAMA: LABA:
	LAMA+LABA: ICS+LABA:
12. Which impact has the G-BA benefit assessment on your decision for a LAMA+LABA combination	1: no influence
	10: very high influence
13. Are you perceiving a change in importance of ICS+LABA and if yes, which change?	Yes/No Open answer
14. What are the reasons for change in ICS+LABA importance?	Open answer
15. Are you actively switching COPD patients from ICS+LABA to LAMA+LABA?	Yes/No
16. Which characteristics must a LAMA+LABA have compared to LAMA or LABA that you switch patients to dual bronchodilation?	Rank with 1 (minor important) to 10 (most important)
	Improvement of FEV1: Improvement of FVC:
	Reduction of exacerbations: Same device:
	Reduction in usage of rescue medication:
	Improvement of dyspnea:
	Improvement of quality of life:
	LAMA+LABA combination contains monotherapy:

disease based on latest medical evidences. Main reasons for the registrations are a better/constant monitoring of COPD patients (44.1%), provision of better COPD-specific training to patients (27.9%), improvement of patients` compliance (17.6%), and financial benefits (16.2%).

Decision criteria for choice of substance: The principal factors upon which lung specialists differentiate between the individual products within the substance classes of LAMAs, LABAs, and LABA/ICS combinations are: the device (48.5%, 36.8% and 45.6%, respectively), the product's duration of action

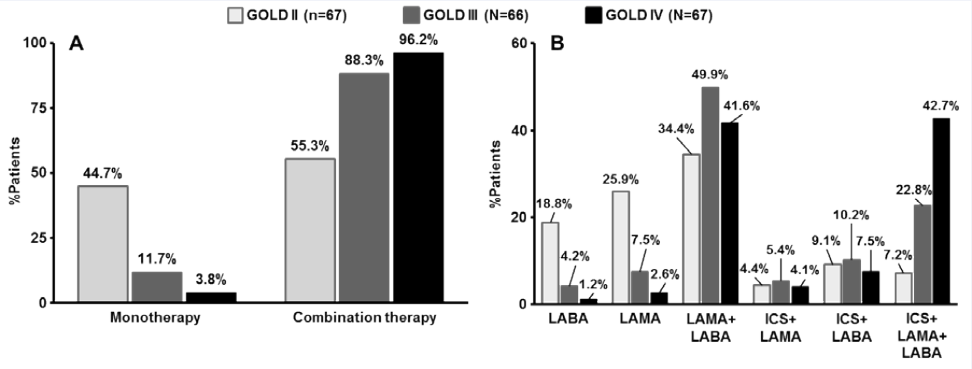

Figure 1 Maintenance treatment prescribed to GOLD II-IV COPD patients by lung specialized practitioners in Germany. A) Monotherapy vs. combination therapy, B) by substance classes.

Table 2: Numbers of newly diagnosed patients with COPD and overall numbers of COPD patients treated by lung specialized practitioners (n=65) per quarter in Germany.

Airway Limitation	Mean number of new diagnoses (SD) / [%]	Mean number of patients treated (SD) / [%]
GOLD 1	25.6 (28.6) / 18.8%	118.1 (137.8) / 17.2%
GOLD 2	54.2 (59.6) / 39.7%	252.7 (179.0) / 36.9%
GOLD 3	36.2 (44.6) / 26.5%	192.7 (164.2) / 28.1%
GOLD 4	21.2 (27.9) / 15.5%	99.0 (85.1) / 14.5%
Total	136.5 (134.7) / 100%	684.7 (481.1) / 100%

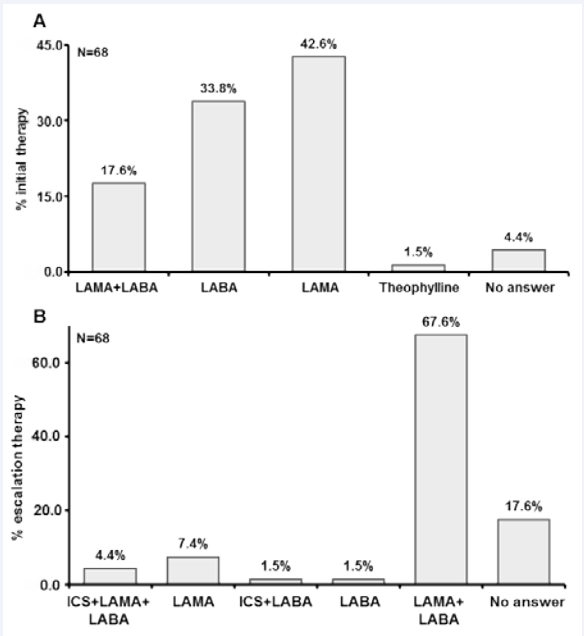

Figure 2 A) Initial maintenance treatment of GOLD II patients, B) escalation therapy for GOLD II patients.

(39.7%, 27.9% and 25.3%, respectively), and the product's side effects (14.7%, 19.1% and 11.8%, respectively). The device and the product's duration of action are also two of the main factors whereby lung specialists differentiate between products in the substance class of LAMA/LAMA combinations (39.7% and 38.2%), the third differentiating factor being published clinical study results for the available LABA/LAMA combinations (16.2%). The mandatory benefit assessment by G-BA, which has been conducted for all fixed-dose LAMA+LABA combinations marketed in Germany, has only a moderate impact on the lung specialist's choice of LAMA+LABA combination. On a scale of 1 to 10, in which 1 denotes "no influence" and 10 denote "very high influence", the mean impact of the G-BA assessment on the choice of LABA/LAMA was 4.31.

The importance of the ICS+LABA combination in the treatment of COPD patients was also evaluated during the interviews with the lung specialists. A reduction in importance of the ICS+LABA combination in the treatment of COPD was recognized by nearly all (89.7%) of the interviewed lung specialists. This change is obvious in a decrease of ICS+LABA prescription (45.6%) and a perceived superiority of LAMA+LABA combinations compared to ICS+LABA in the everyday use by patients (32.4%). Besides, a total of 72.1% of interviewed physicians mentioned that the results of clinical studies are responsible for the reduction in importance of the ICS+LABA combination, and the FLAME study in particular (which showed that the LABA+LAMA combination, Indacaterol/Glycopyrronium was more effective than Salmeterol/Fluticasone in preventing COPD exacerbations) was named by 41.2% of interviewed lung specialists. Besides clinical study results, the lung specialists own experiences and ICS side effects, such as increased risk of serious pneumonia events, were mentioned by 20.6% and 14.7% of lung specialists, respectively, as main reasons for the decrease in importance of ICS+LABA. Furthermore, 77.9% of German pneumologists stated that they are actively switching patients from ICS+LABA combinations to LAMA+LABA combinations.

Finally, the characteristics and benefits that fixed LAMA+LABA combinations must demonstrate compared to the monotherapies in order for lung specialists to switch COPD patients from monotherapy (LAMA or LABA) to LAMA/LABA combinations were investigated (Figure 3). The characteristics considered more important were (in decreasing order of importance): improvement in quality of life (mean score provided by specialists of 8.31), improvement of dyspnea (mean score: 8.01), and reduction of exacerbations (mean score: 7.43).

Discussion

In this interview study, 68 lung-specialized practitioners in Germany were interviewed on management of COPD. Based on IMS Health data, a total of 1,261 lung specialized practitioners were actively working in Germany in 2016 [9]. The sample size of 68 interviewed lung specialists corresponds to 5.4% of the total population and, therefore, should allow the study to show at least trends in the management of COPD in Germany.

Since the total number of COPD patients in Germany remains unclear, the findings of this study provide some information on this topic. Our study reveals that lung specialists in Germany are treating 685 COPD patients (GOLD I-4) on average per quarter. If the lung specialists who participated in this study are representative of the total population of lung specialists in terms of numbers of COPD patients, it can be estimated that there are approximately 3.5 million COPD patients visiting lung specialists per year, which correspondents to a COPD prevalence of ~4.2%, based on an estimation of the German population of 82.8million [10]. Taking into consideration that patients diagnosed with COPD are in general 40 years or older [1], our results reveal a COPD prevalence of ~9%, within the German population of 50 million being 40 years or older [10]. The BOLD study revealed COPD prevalence (GOLD I-IV) in Germany within the same age group of 13.2% [2], which is similar to our findings.

Recently published data from DACCORD study showed that of participating COPD patients, 17.6%, 48.6%, 27.9%, and 5.9% were in the airway limitation severity stages GOLD 1, GOLD 2, GOLD 3, and GOLD 4, respectively [11]. Compared to DACCORD, our study showed the proportion of GOLD 4 COPD patients to be slightly higher (14.5%) and the proportion of GOLD 2 patients to be slightly lower (36.9%), whereas proportions of GOLD 1 (17.2%) and GOLD 3 patients (28.1%) were comparable.

The above-mentioned number of 685 COPD patients per lung specialized practitioner per quarter shows a high workload for this group of medical specialists. Since, the German population is growing older, an increase in numbers of COPD patients is likely. It is already known that the management of lung disease in general is at risk of deteriorating because of heavy workload [4]. Therefore, to cope with a potential increase in the numbers of patients with COPD in coming years, the number of lung specialized practitioner should increase.

Our data indicate that a main maintenance treatment option prescribed by pneumologists in COPD severities GOLD 2, 3, and 4 in Germany is dual bronchodilatation with LAMA+LABA with prescription rates of 34.4%, 49.9% and 41.6%, respectively.ICS containing regimens are prescribed to 20.7%, 38.4% and 54.3% of GOLD II, GOLD III and GOLD IV COPD patients, respectively

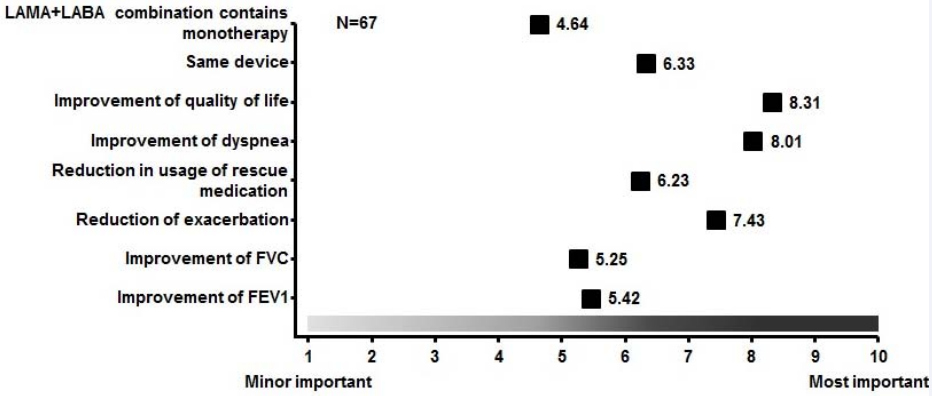

Figure 3 Mandatory benefits/characteristics fixed LAMA+LABA combinations must demonstrate compared to LAMA- or LABA-monotherapy that lung specialists switch from mono to dual bronchodilation.

(Figure 1). These numbers are in the range of overall patients treated with ICS containing regimes in Germany (39.4%) published by Worth et al. (2016) [11].

These high ICS prescription rates (ICS+LABA, ICS+LAMA, ICS+LAMA+LABA) could be interpreted as contradictorily to our data that 89.7% of interviewed lung specialized practitioners mentioned a decrease in the importance of ICS and that most of them are switching ICS+LABA patients to LAMA+LABA (77.9%). Interviewees mentioned that the main reasons for change of importance of ICS are studies and especially 2016 published FLAME study. FLAME showed superiority of LAMA/LABA combination Indacaterol/Glycopyrronium to ICS/LABA combination Fluticasone/Salmeterol in the reduction of the annual rate of COPD exacerbations [5]. In our view, this mismatch in prescription behavior and perceived decrease in ICS+LABA importance must be further investigated to identify possible prescription barriers. This is significant given that in the GOLD 2017 Global Strategy, ICS/LABA combination is no longer the recommended first-line treatment for patients with frequent exacerbations [1].

Assuming that, GOLD 2 patients are mainly non-frequent exacerbator, the initial maintenance treatment given to GOLD 2 patients and the first escalation step in Germany shows a much stronger correlation to GOLD [1], starting with LAMA or LABA monotherapy and escalating to LAMA+LABA combination in the event of persistent symptoms or exacerbations (Figure 2). Nevertheless, GOLD II patients are treated with ICS containing regimens as well (Figure 1). The main reasons cited by the lung specialists for prescription of ICS to GOLD II patients are asthma-COPD overlap (ACO), formerly called ACOS (asthma-COPD-Overlap-Syndrome) [12], frequent exacerbations and short-term escalation following an exacerbation, and of these, ACO was the most frequently cited (by 39.7% of lung specialists). To the best of our knowledge, the prevalence of ACO in Germany is unclear. The Association of Statutory Health Insurance Physicians Berlin (KV-Berlin) recently published estimations that 15-25% of all obstructive lung diseases are ACO [13]. Data from Italy suggest that the prevalence of ACO in the age group of 65-84 years is about 4.5%and COPD alone is present in 13.3% of patients in the same age group [14]. Similar data are published from the U.S. where the prevalence of ACO among a study population of 80,498 patients at age 35 or older was 3.2%compared to 6.0% for COPD alone [15]. A recent conference contribution by Novkovic et al. (2017), revealed a prevalence of ACO among 605 COPD patients of 10.9% [16]. It is likely that the prevalence of ACO in Germany is comparable to the prior mentioned numbers and should be further investigated. Especially, as treatment should be based on an individualized assessment of the characteristics of the patient's COPD [17], and ICS-containing regimens are recommended for patients with ACO [12], but not for patients with COPD unless they suffer persistent exacerbations despite treatment with long-acting bronchodilators. Besides, it is well known that ICS is associated with a higher rate of pneumonia in COPD patients [6,18].

As shown in Figure 3, lung specialized practitioners switch COPD patients from monotherapy (LAMA or LABA) to dual bronchodilatation with a LAMA+LABA combination if the combination shows the following three benefits compared to monotherapy (in decreasing order of priority): 1. Improvement of quality of life; 2. Improvement of dyspnea; 3. Reduction of exacerbations. These characteristics correspond to the goals of the GOLD strategy for the treatment of stable COPD patients, to "reduce symptoms" and "reduce risk" and are very consistent with the GOLD recommendations to switch from monotherapy to LAMA+LABA in case of persistent symptoms and/or severe dyspnea [1]. In contrast, pneumologists in Germany mainly differentiate between LAMA+LABA combinations based on device (39.7%) and duration of action (38.2%), but only by 16.2% on study results. In our view, the impact of studies must be much higher, since studies allow the necessary monitoring if a LAMA+LABA combination is improving quality of life and dyspnea and is reducing rate of exacerbations. Particularly, since to the best of our knowledge only the LAMA+LABA combination Indacaterol/Glycopyrronium reduced the rate of COPD exacerbations significant compared to a LAMA (Glycopyrronium) in COPD patients with severe/very severe (GOLD 3 and 4) airflow limitation and an increased risk for exacerbations with one or more exacerbations in the previous year [19]. Besides, a recently published Cochrane review reveals significant differences between LAMA+LABA combination regarding the prevention of COPD exacerbations compared to ICS+LABA, with only Indacaterol/Glycopyrronium showing superiority over ICS+LABA [20].

CONCLUSIONS

In conclusion, our study shows a high workload for lung specialized practitioners in an ageing German society. Lung specialized practitioners in Germany show a strong knowledge on recent publications and the GOLD treatment recommendations, by reporting an increase of importance for LAMA+LABA in COPD management. Nevertheless, the prescription rates of ICS containing regimens in the management of COPD remain high in Germany. A reason might be the concerns of the presents of ACO. Especially, since the exact number of ACO a patient in Germany remains unclear. Therefore, future studies should focus on the prevalence of ACO in Germany to improve medical care for COPD as well as ACO patients and to management according to the characteristics of the diseases.

DECLARATION OF CONFLICT OF INTERESTS

OR and LM are working in pharmaceutical industry for UCB Innere Medizin GmbH & Co. KG.

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