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COPD

Consistency Between Diagnostic and Therapeutic Decisions in COPD Patients with Respect to the Recent Guidelines

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Abstract

Objective: To investigate the reports provided for chronic obstructive pulmonary disease (COPD) patients by a certain pulmonologist board, and to determine their consistency with the recent national and international guidelines regarding diagnosis and management. **Design**: One hundred and six valid official reports provided by physicians working in the chest department of a university hospital were evaluated retrospectively according to the information available on diagnostic criteria and treatment options. **Results**: Mean age of the patients was 62±11 years and 89% were males. Diagnostic information given in the reports included symptoms, physical signs, basic pulmonary function test results, bronchodilator test results, arterial blood gases, chest X-ray and thorax CT/HRCT findings (in 94.3%, 47.2%, 56.6%, 5.6%, 16%, 7.5% and 4.7% of the reports, respectively). Functional stage (FEV1 as percent of predicted) was declared in 49.1% of the reports. Therapeutic decisions included short-acting β2-agonists, long-acting β2-agonists, short-acting anticholinergics, inhaled steroids, theophylline, expectorants, oral steroids (when needed), antibiotics (when needed), cromones, anti-leukotrienes, nebulizers, long-term oxygen therapy and non-invasive mechanic ventilator (in 87.7%, 86.8%, 67%, 72.6%, 73.6%, 67%, 25.5%, 55.7%, 0.9%, 0.9%, 41.5%, 10.4% and 3.8% of the reports, respectively). **Conclusion**: The diagnostic and therapeutic reports for COPD patients provided in our department reveal some inappropriateness in diagnosis and treatment according to the recent guidelines. Although it is not necessarily indicative of improper practical approach in drug prescription, the results may be accepted as a warning for the requirement of an urgent action plan on public health politics in Turkey.

Keywords: COPD, diagnosis, therapeutics, guidelines, health system

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INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a debilitating chronic lung disease that causes progressive impairment in breathing ability in affected patients. According to the World Health Organization (WHO), it is suggested that 2.75 million people die annually worldwide because of COPD. It is also expected that COPD will rise from seventh to fifth place as a cause of morbidity by the year 2020 [1]. In Europe, the prevalence is 4-10% and the mortality rate varies between 6-95 per 100,000 [2]. It is predicted that 2.5-5 million people have COPD in Turkey, and the disease ranks fourth as a cause of death [3,4]. In a recent study, it was concluded that the burden of COPD as a smoking-related condition appears to be more substantial than the smoking-related impact on cardiovascular disease and lung cancer. In light of these data, COPD deserves more attention in the health care sector [5].

Cost to the society as a result of COPD is excessive, with a global burden of morbidity as well as mortality. By the year 2020, COPD is expected to rise from twelfth to fifth place as a cause of disability-adjusted life years lost (DALYs). In the European Union, it has been estimated that the cost of COPD in terms of annual work force loss is 28.5 billion €, while it is 4.7 billion € for out-patient management, 2.9 billion € for in-patient management and 2.9 billion € for drugs [2]. COPD, via the medical expenses and workforce loss attributed to the disease, contributes to serious economic and social burden in all countries. It has been reported in the United States that the secondary and indirect cost associated with COPD was 23.9 billion $ in 1993, versus 12.6 billion $ for asthma, 7.8 billion $ for pneumonia, and 1.1 billion $ for tuberculosis [3]. Thus, the necessity of discussing the diagnosis and treatment of COPD as dictated by the national health system is obvious.

According to a declaration by the Turkish Health Minister, 80% percent of all health expenses are covered by the Turkish government, and 40% of that amount consists of drug expenses. Turkey is cited as having the highest drug expenditure among the Organization for Economic Cooperation and Development (OECD) countries [6].

In Turkey, it is obligatory that medical specialist boards submit official reports for many chronic health problems with high cost or long-term treatment requirements. They must be declared to the general practitioners or medical markets for governmental refund of the cost. Although these reports are supposed to be used as a supervision tool

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for health economics, to our knowledge, there is no other study which has investigated whether these kinds of suggestions were reasonable, especially for chronic diseases with high economic burden like COPD. The aim of this study was to review the reports for COPD patients given by a certain pulmonologist board in view of the recent guidelines and evidences. We believe that some of the information will be useful for the national legislatives, health insurance regulators and the government.

METHODS

The reports provided by a local board of pulmonary specialists (working in the Chest Department of Trakya University Hospital, Edirne, Turkey) during the last 24 months (2002-2003) concerning diagnosis and treatment in COPD patients were studied retrospectively.

The request for the report was made by each patient diagnosed in the out-patient or in-patient clinic. The physician who made the diagnosis was asked to submit a written order giving the diagnostic criteria and selecting the treatment options from among a previously fixed list. Each report was signed by three doctors specialized in chest medicine. The reports were valid for two years and were required not only for the governmental refund of drugs and medical devices but also to guide general practitioners in the management of stable COPD patients in primary health care facilities.

For a descriptive study design, the number of the reports including related information was calculated. In addition to basic demographic features like age and gender, symptoms, physical signs, pulmonary function tests (especially FEV_1 and/or FEV_1/FVC parameters), bronchodilator reversibility test results, arterial blood gases (ABG) analysis, and findings of radiographic evaluation declared in the reports of each COPD patient were studied as diagnostic criteria. The result of ABG analysis was obligatory for the official decision for long-term oxygen treatment (LTOT), non-invasive mechanical ventilation (NIMV) and invasive mechanical ventilation (IMV). For the patients whose pulmonary function test results were declared in their reports, the severity of the disease was determined in five stages (Stage 0 to 4) according to the Global Initiative for Obstructive Lung Diseases (GOLD) criteria [9].

The treatment choices were evaluated as orders including any of the following: short-acting beta-2 agonists, short-acting anticholinergic, long-acting beta-2 agonists, inhaled steroids, theophylline, expectorants, oral steroids, antibiotics, inhaled cromones, anti-leukotrienes, and the decisions for using nebulizer, long-term home oxygen treatment and NIMV at home. The number of reports including any of the above was calculated separately for each option. The descriptive analyses were used for statistical determination. The data were examined on the basis of recent national and international COPD guidelines and national health system features. At the time of the reports, the valid guidelines were the first GOLD report and the Guideline of the Turkish Thoracic Society [3,9]. The long-acting anticholinergic was not available in the market at the time of the study.

RESULTS

One hundred and six reports were evaluated. Ninety-four patients (89%) were males, and the mean age of all COPD patients was 62±11 years.

Although the primary diagnosis was COPD in all reports because of the study design, a secondary diagnosis was given in 25 reports (23.5%) and a tertiary diagnosis was found in five reports (4.7%). In 12 of those reports, cor pulmonale, obstructive sleep apnea, respiratory failure and asthmatic bronchitis were the accompanying diagnoses in 5, 1, 5 and 1 patients, respectively.

When the data related with COPD diagnosis was evaluated, the distribution of written criteria was as follow: respiratory symptoms in 94.3%, physical examination findings in 47.2%, pulmonary function test results in 56.6% (FEV_1 in 49.1%, FEV_1/FVC in 47.2%), result of the reversibility test in 5.6%, ABG analysis in 16%, chest roentgenogram in 7.5%, and thoracic CT and/or HRCT findings in 4.7% of the reports (Table 1). In 74% of the reports without any data for ABG analysis, the FEV_1 was

Table 1. Diagnostic information provided in the official COPD reports

	Symptoms N (%)	Signs N (%)	Spirometry N (%)	FEV1 N (%)	FEV1/FVC N (%)	Bronchodilator test N (%)	Blood gases N (%)	Blood gases needed N (%)	Chest X-ray N (%)	Thorax CT / HRCT N (%)
Yes	100 (94.3)	50 (47.2)	60 (56.6)	52 (49.1)	50 (47.2)	6 (5.6)	17 (16.0)	8 (36)	8 (7.5)	5 (4.7)
Total n	106	106	106	106	106	106	106	31	106	106

Table 2. Treatment orders obtained from the reports according to GOLD stages

Treatment	GOLD Stages 0 n=1	II n=20	III n=19	IV n=12	No information n=54	Total n=106
Short-acting beta-mimetic %	100	95	84.2	83.3	87.0	87.7
Short-acting anticholinergic %	100	50	47.4	50	83.3	67.0
Long-acting beta-mimetic %	100	90	78.9	83.3	88.9	86.8
Inhaled steroid %		95	68.4	75	66.7	72.6
Theophylline %	100	85	68.4	58.3	74.1	73.6
Expectorant %		65	57.9	66.7	72.2	66.0
Oral steroid %		20	15.8	16.7	33.3	25.5
Antibiotic %		70	47.4	41.7	57.4	55.7
Inhaled cromone %					2.1	0.9
Anti-leukotriene %					2.1	0.9
Nebulizer %		10	47.4	16.7	57.4	41.5
LTOT[a]					20.4	10.4
NIMV[b]					7.4	3.8
Home ventilation					2.1	0.9

[a]LTOT: Long-term oxygen treatment
[b]NIMV: Non-invasive mechanic ventilation

found below 40% of predicted value. According to pulmonary function test, especially FEV_1 data, the GOLD stage of the patients was determined as at risk in 1 case (0.9%), Stage II in 20 cases (18.9%), Stage III in 19 cases (17.9%), and Stage IV in 12 cases (11.3%); in 54 cases (50.9%), the stage could not be determined.

Treatment decisions were found as follows (Table 2): short-acting β_2-agonists in 87.7%, long-acting β_2-agonists in 86.8%, short-acting anticholinergic in 67%, inhaled steroids in 72.6%, long-acting oral theophylline in 73.6%, expectorant in 67%, oral steroids (when needed) in 25.5%, antibiotics (mentioned as when needed, no specific agent addressed) in 55.7%, inhaled cromones in 0.9%, and anti-leukotrienes in 0.9% of the reports. Nebulizers were prescribed in 41.5% of the reports while LTOT was ordered in 10.4%, NIMV at home in 3.8% and IMV at home in 0.9% of the reports. The distribution of medical recommendations according to the COPD stage is also included in Table 2. No data were obtained related with the disease severity in the reports in which LTOT, NIMV or IMV treatment was prescribed.

DISCUSSION

The official reports for COPD patients given in our department showed some inappropriate practical implementation of diagnostic methods and treatment recommendations as given in the guidelines. These results indicate that there are no obligatory definitions in the official reports ordered from governmental agencies as well as a lack of auditing.

It is estimated that people with chronic lung diseases cannot obtain health care at acceptable standards in many countries where those diseases are frequently seen. The limited crucial resources are being exhausted via excessive and unnecessary drug use, especially of antibiotics. In addition, there are many people who can never access the health care facilities and drugs [7]. There are also some difficulties in generalization of the guidelines in many communities and health care systems, which complicate their widespread applications [7].

In 41 COPD guidelines from 42 countries, there is a consensus on the role of risk factors, symptoms and spirometry for COPD diagnosis, but the details and necessities differ widely. Presence of spirometry, the ratio for FEV_1/FVC and FEV_1 as percent of predicted, response to bronchodilator agent, smoking history, symptoms, age, and irritants other than cigarette smoke were admitted as obligatory in 83%, 54%, 22%, 15%, 10%, 5%, 2%, 2% of those guidelines, respectively [8].

In the GOLD guideline, presence of the symptoms is not obligatory [9]. Ninety-four percent of all reports evaluated in the current study contained information about respiratory symptoms. Additionally, 47% of the reports included information about the physical signs.

Spirometry and FEV_1 (especially post-bronchodilator) are declared in GOLD as essential either in COPD diagnosis or in determining the treatment in stable COPD [9]. In the current study, information regarding pulmonary function tests and FEV_1 was not found in 51% of the reports. This may only be indicative of a lack of enforced regulations, but it is also a limiting factor for verifying the appropriateness of the decisions taken. In our opinion, this result most likely reflected a lack of diligence in reporting the results rather than indicating that spirometry was not performed. In 83% of the guidelines, spirometry is admitted as an obligatory criterion [8].

Chest X-ray is not essential for COPD diagnosis, but may be useful to exclude other possible diagnoses. Especially in the countries with high tuberculosis incidence, it is reasonable to suggest chest X-ray at least in the first evaluation. In this study, chest X-ray results were reported

in only 7.5%. We suggest this was due to lack of official order as with other errors in these reports.

Arterial blood gas analysis should be performed for a patient whose FEV_1 is below 40% of predicted or who has clinical signs of respiratory failure or cor pulmonale [9,10]. In the current study, ABG analysis was recorded in only 16% of the reports. When considered with the FEV_1 values, there were no data about ABG analysis in 64% of the reports in which it was necessary. Thus, the indication was not clearly declared in the majority of the reports in which LTOT, NIMV or IMV treatment was prescribed.

Inhaled bronchodilators are the main drugs for improving symptoms and pulmonary functions in COPD. It has been shown that all bronchodilators may increase exercise capacity of the patient even though they have no marked increasing effect on FEV_1 [10]. In the current study, short-acting β_2-agonist and short-acting anticholinergic were documented in 88% and 67% of the reports, respectively. Those drugs may be suitable for any stage of COPD. Inhaled ipratropium has been admitted as a short-acting and more effective agent in COPD, and it is safer because of less local absorption compared to short-acting β_2-agonists.

In the current study, long-acting β_2-agonists were documented in 87% of the reports. Except for one patient misdiagnosed as Stage 0, they were given to 90% of Stage II COPD patients. Applicable guidelines promulgated at the time period of the current study were the first version of GOLD and the adopted Turkish Thoracic Society COPD guideline, which have no indication for long-acting β_2-agonists in Stage II COPD patients. Furthermore, long-acting anticholinergic agent was not available in the market at that time. Those treatment choices have not been suggested for routine utilization in COPD because of the cost-effectiveness issue in developing countries [10]. Furthermore, in a recent English guideline, NICE, long-acting bronchodilators are not suggested in the first-line treatment [11]. GOLD guidelines approve choice of beta-mimetic, anticholinergic, theophylline or combinations of those drugs based on the availability and the effectiveness on symptom relief, and considering the adverse effects of the drug [12].

In the current study, chronic theophylline treatment was recorded in 73.6% of the reports. Theophylline is one of the effective and less expensive drugs in COPD treatment. Because of the toxicity problem, it is suggested as a third-line treatment in the major guidelines. Its combination with short- and long-acting β_2-agonists can exert additional benefit. On the other hand, its removal from the chronic treatment has been shown to trigger worsening [13]. The anti-inflammatory effect of theophylline has been reported recently as an important effect, especially for the steroid-resistant COPD and current-smoker patients [14].

The indication of steroids in COPD is limited. It has been shown that high-dose inhaled steroids did not diminish functional loss in COPD [15,16]. However, high-dose inhaled steroids (fluticasone 1000 mcg daily) have been shown as effective in decreasing the number and severity of exacerbations, and in improving symptoms in steroid-responsive patients, with less than 50% predicted FEV_1 and two or more exacerbations in one year [17]. In most of these studies, inhaled steroids have been prescribed in combination with long-acting β_2-agonists. Though GOLD suggests inhaled steroids for Stage III and IV patients, it was found in the current study that those drugs were prescribed for the majority of Stage II COPD patients.

Long-term oral steroids are not suggested in the major guidelines [9]. In the current study, oral steroids (when needed) were ordered in 26% of the reports. As found for inhaled steroids, in the majority of patients who were on oral steroids, the indication was not consistent with the suggestions from guidelines.

Inhaled cromones and anti-leukotrienes are not among the treatment choices for COPD patients. Therefore, one patient given that prescription was erroneously considered to have asthma instead of COPD.

There is not yet sufficient evidence showing the benefit of mucoactive-expectorants in COPD. They are not suggested in the routine treatment [9]. But these drugs may be prescribed for a few patients with thick sputum. Although routine use of N-acetyl cysteine is not encouraged, it might be helpful to decrease the number of exacerbations in those patients who experience them frequently [12]. Thus, it should not be expected to find mucoactive-expectorants or N-acetyl cysteine in many reports as one of the long-term treatment choices.

According to GOLD, nebulizer treatment is not suggested in routine use because of its high cost, special care requirement, and the possibility of increasing adverse effects, unless its use is expected to enhance the benefits [8,12]. In the current study, there was a high rate of documentation of nebulizers and drugs for nebulization (in 42% of the reports), without mention of the specific indication.

Long-term oxygen treatment (LTOT) is a cardinal non-drug treatment for Stage IV COPD patients. At least 15 hours a day oxygen supplementation was shown as survival benefit [8]. Though LTOT should be prescribed according to certain indications, in the current study, no criterion was found in the LTOT orders given to 10.4% of the COPD patients.

Non-invasive mechanical ventilation at home was prescribed for four patients in the current study. None of them was described according to the severity of the disease or the indications of the therapy. Although there have been many studies related with NIMV, no conclusive results have been reported to date for management of stable COPD patients , except for the possible benefit in a group of patients with chronic hypercapnia.

Invasive mechanical ventilation at home was ordered for one patient. In GOLD, this issue is rather controversial and there is no guidance for the criteria of patient selection [9].

The results of the current study have led to a panel discussion among chest physicians working in our clinic who are responsible for producing official reports. In a local setting, this study is worth performing if only for achieving a consensus between a certain group of physicians. Beyond that benefit, however, we believe there is a potential benefit of appropriately adapting the health care politics of the country.

In conclusion, although the guidelines and evidence-based practical implementation guides for COPD management at national and international levels have been available, Turkish governmental perception and implementation have not yet been established. As a result, the expert clinician reports for COPD treatment may differ widely without basis on any consensus. That consequence has a potential to seriously increase the national financial burden. The results of the current study may be accepted as a warning for the requirement of an urgent action plan on public health politics in Turkey.

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