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"The Italian Project "COPD 270°": A Collaborative Approach for Identifying Patients with Undiagnosed Chronic Obstructive Pulmonary Disease (COPD) In Primary Care

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Abstract

Aim: The aim of this study was to improve the primary care setting the management of Chronic Obstructive Pulmonary Disease (COPD), restoring a synergistic relationship of cooperation between general practitioners (GPs) and pulmonologists.

Methods: In November 2009, a project called "COPD 270° "was undertaken by a group of GPs, concerning the diagnosis of COPD in patients aged between 35 and 65 years and at risk due to their smoking status. The involved group consisted of eight GPs, a nurse, three secretaries and two graduates in medicine. The study was carried out in November 1st 2010-October 31st 2011. Based on the acknowledged critical issues in the approach to the diagnosis of COPD in general practice in Italy, an operative model, suitable for the general practice setting, was designed. This included readily available diagnostic tools, quick to use, and low cost (audit, medical history, "screening", minimal advice, collaboration with pulmonologists).

Results: At the end of the follow-up year, 3,751 patients (61.5%) were evaluated and had the full set of data. 724 (19.3%) active smokers were identified. Within those with a pack-year >10, 657 examinations were performed with Piko 6 (170 patients with borderline Piko (70/79) (25.9%) and 72 patients (10.9%) with values of Piko <70). GPs required 206 spirometry. The "minimal advice" has been bestowed and recorded in 412 patients. At the end of the observational year, the overall data demonstrated a significant increase of new diagnoses of COPD (+65 cases), a good efficiency in recording the "smoke habit" data (88.7% versus 71.5% initial), and an increase in the number of spirometry prescribed. Another significant data obtained from the "270° COPD" study concerns the intervention on smoking habit; in fact, after more than one year by the end of the study, half of the patients with newly COPD diagnosed (stage I) persisted in smoking cessation.

Conclusions: This study showed a greater awareness on the part of GPs of the problem "COPD"; an increase in the number of early GOLD stage diagnosed cases of COPD; and a productive professional synergy between GPs and pulmonologists.

Keywords: Chronic Obstructive Pulmonary Disease (COPD); Primary care; Piko 6; Smoking cessation

Introduction

Chronic obstructive pulmonary disease (COPD) is one of the most common lung disease and the fourth leading cause of death worldwide [1]. International data suggest that only a few cases (9 to 22%) are correctly diagnosed [2]. There is an evidence indicating that many patients, at least in primary care, are diagnosed with COPD when the airway obstruction induces significant changes in lifestyle (dyspnea) or during an acute respiratory illness (exacerbation) [3,4]. Identifying cases of undiagnosed and clinically significant COPD in primary care should prompt an effective medical treatment and improve short- and long-term health outcomes [5,6]. In November 2009, a project called "COPD 270° "was undertaken by a group of general practitioners (GPs), concerning the diagnosis of COPD in patients aged between 35 and 65 years and at risk due to their smoking status. Aim of the study was to improve, in primary care setting, the management of COPD patients, restoring a synergistic relationship of cooperation between GPs and pulmonologists. The involved group consisted of eight GPs, a nurse, three secretaries and two graduates in medicine. The study was carried out in November 1st 2010-October 31st 2011. Based on the acknowledged critical issues and the unmet needs in the approach to the diagnosis of COPD in general practice in Italy (Table 1), an operative model, suitable for the general practice setting, was designed. This included readily available diagnostic tools, quick to use, and low cost (audit, medical history, "screening", minimal advice, collaboration with pulmonologists). The study group, real-life based, attempted to achieve data on: 1) the current tobacco smoking in all patients referred to the clinics as part of an "opportunistic" intervention; 2) the characteristics of the population at risk according to clinical history; 3) the subpopulation of patients, with smoking habits, who had to be referred to spirometry for diagnosis of COPD; 4) the use of a "minimal advice" approach in currently smoking patients; 5) the identification of COPD patients at early stages by pulmonary function test; 6) the possibility and opportunity of implementing a model of active collaboration with pulmonologists according to the Diagnostic-Therapeutic Welfare Path (in

Italian called "PDTA") for COPD issued by the Local Health Authority (in Italian called "ASL") of Brescia [7].

Patients and Methods

This study describes the results of observations, and interventions carried out as an easy to applicable medical methodology during the normal course of working GPs activity. At the working GPs group called "San Luca COPD 270° Screening Study Group" participated 8 GPs (Males/Females: 4/4; age range: 52-58 years). All the GPs were working in the same clinic (Ambulatorio Medico "San Luca", Villanuova sul Clisi, Brescia, Italy). As summarized in (Figure 1), the study began with a preliminary phase in April 2010, with a meeting in collaboration with pulmonologists on specific issues update on COPD.

To evaluate the effectiveness of the intervention to be undertaken, baseline data provided by 8 GPs in the group were initially examined (Table 2) which showed an average prevalence of COPD in their patients by 5.1%. In a population-based study in which COPD was diagnosed based on the assessment of lung function by means of spirometry, the so called "Burden Of Obstructive Lung Disease" (BOLD) study, higher prevalence values between 8.2 and 19.1% in adults 40 years of age or older were found [8]. The examination of the data in the previous 2 years also showed that the spirometry was underused with an average of just over 1 spirometry per month per GP (respectively 103 and 119 in the 2 years preceding the study). The project also included all patients, age range: 35-65, who had come to the clinic for any reason should be investigated about the smoking status (Table 2) that shows the baseline data. In addition, a "warning" entered into the electronic folder reminded the GP that the patient was suitable to enrollment in the project. At this stage of the study, GP could detect four possibilities:

Patient who had never smoked

In this case the GP cancelled the warning and he was limited to record the data "patient non-smoker";

Table 1: The critical issues and unmet needs of Italian GPs on the management of COPD.

• Smoking habit incompletely investigated
• Late diagnosis, frequently at the most advanced and symptomatic GOLD stages
• Low prevalence in the initial GOLD stages
• Inaccuracy in the staging and classification for diagnostic methodological deficiencies
• The majority of patients have no spirometric diagnosis
• The incompleteness and unreliability of essential diagnostic data (no spirometric data, i.e.: FEV1)
• Therapy often disproportionate to the severity GOLD stage of the disease or not commensurate to the same
• Little attention to the evaluation of the level of patient adherence to continuous therapy

Patient formerly smoker

If not already done, the words "Personal history of tobacco use" was inserted together with the "pack-year" count. In the case of a pack-year equal to or greater than 10, a screening test by the tool called "PIKO 6" (see below) was offered. The detected value with the Piko 6 directly obtained in the study of GPs determined subsequent procedures (Figure 1).

Patient currently smoker

In this case he/she was classified in the electronic folder as "Personal history of tobacco use", and underwent a brief counseling, Fagerström test for nicotine dependence and motivational Mondor test [9-10], and performance of the screening test using "Piko 6" (parameter used : FEV1/FEV6 considered equivalent to Tiffenau index). If the value was below 70% a confirmatory spirometry with any of bronchodilation test for suspected COPD. If the value was greater than 80, it not instead gave indication to spirometry. In the case of result between 70 and 79, it is left to the clinical evaluation of the treating physician the opportunity to prescribe the execution of a spirometry. In any case, the clinical judgment of the physician could lead to the need for deepening spirometry regardless of the outcome of the screening test.

Previous medically ascertained diagnosis of COPD or asthma

The GP proceeded to the clinical evaluation and medical history to indicate the need for spirometric evaluation.

Piko-6 Digital Lung Function FEV-1 & FEV-6 Meter for COPD by nSpire allows to easily measuring FEV6 and FEV1/FEV6, bringing a new level of effectiveness to the monitoring of COPD [11]. An easy and cost-effective solution to patient screening and monitoring, PiKo-6 acts as a reliable indicator of the need for full spirometry and provides continuous assessment of lung function. The nSpire PiKo-6 Electronic FEV1 / FEV6 Meter measures both the Forced Expiratory Volume in the first second of expiration (FEV1), and the Forced Expiratory Volume in the first six seconds of expiration (FEV6). The PiKo-6 Lung Health Monitor displays and stores the test results and the ratio of FEV1/FEV6. FEV6 may be used as an alternative to Forced Vital Capacity (FVC). All the patients agreed to participate in the study and signed an informed consent form.

The differences between each treatment group and the symptom scores were analyzed by the Student's unpaired t-test.

Results

As detailed in table 2, the baseline data of patients are comparable. Patients to be examined accounted for about 50% of the total (6,144 of 12,275). At the end of the follow-up year, 3,751 patients (61.5%) could be evaluated and had the full set of data. 724 (19.3%) active smokers were identified. Within those with a pack-year >10, 657 examinations were performed with Piko 6 noting the following data: 170 patients with borderline Piko (70/79) (25.9%) and 72 patients (10.9%) with values of

Table 2: COPD 270° Project – Basal and Post-Intervention Data.

Basal values	Post-Intervention values
Patients (total) : 12.275	Piko 6 with pathological values : 242
Patients with age range from 35 to 65 years: 6.144 (50, 05%)	Spirometry performed:164
Number of spirometry performed in the period 2008-09: 103	Spirometry with pathological values: 52
Number of spirometry performed in the period 2009-10: 119	GOLD stage distribution: Stage I: 46 pts (88.3%); Stage II: 4 pts (7.8%); Stage III: 2 pts (3.9%); Stage IV: 0 (0%)
Patients diagnosed with COPD already known: 624 (5, 08%)	
Patients evaluated for smoking status (age range from 35 to 65 years): 3.751 (total: 6.144) (61.05%)	
Active smokers: 724 (19, 3%) Active smokers with Pack-Year ≥ 10: 657 (17, 51%)	

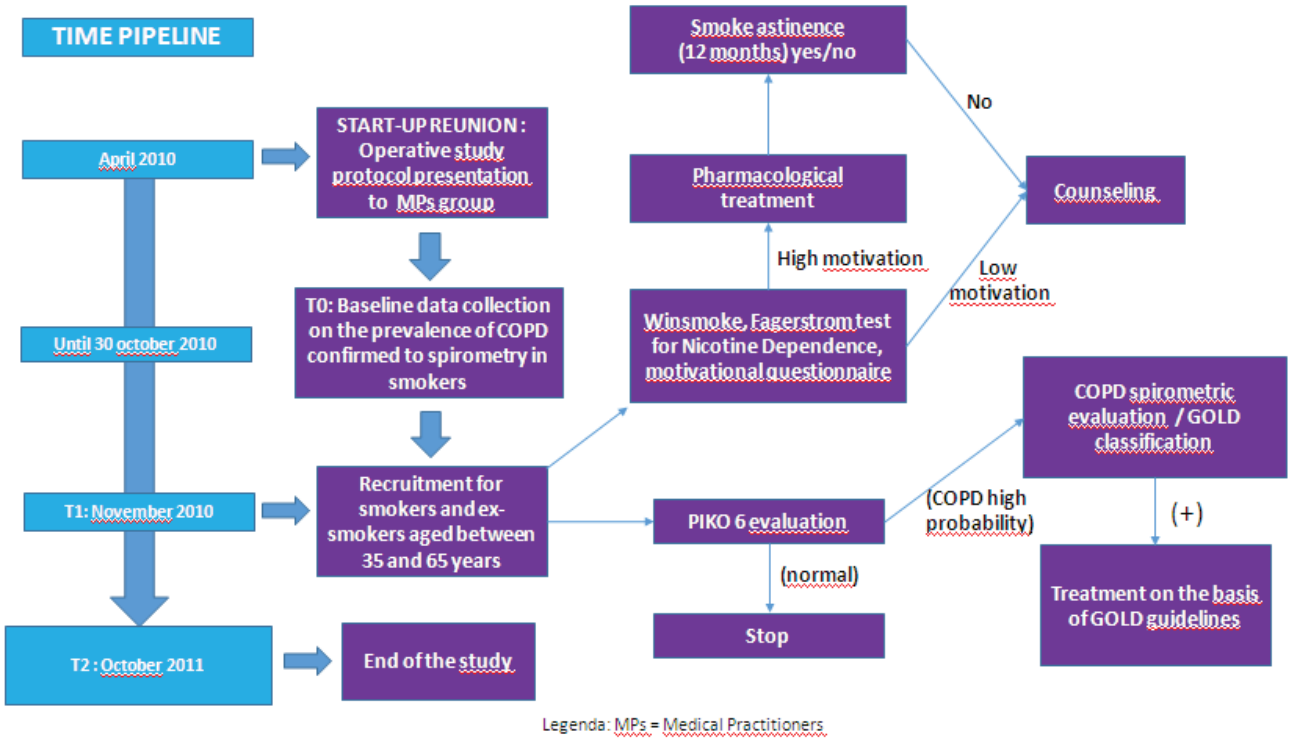

Figure 1: Pipeline of the study illustrating the organizational aspects.

Piko <70. The data collected on active smoking were slightly lower than the national average (19.3% *vs.* 21.7%) (DOXA-ISS 2010 survey) [12]. Based on these data the GPs required 206 spirometry, in less than a third of patients showed a smoking habit consumption beyond the limits of the 10 PY. It was subsequently verified that the performed spirometry were 164; 42 exams in less than those initially prescribed by GPs. The "minimal advice" has been bestowed and recorded in 412 patients. Table 2 shows also the results produced by the methodology of the "COPD 270°" study in terms of new diagnoses. The new diagnoses evidenced that 88% patients could be classified at as first stage of COPD, since it is asymptomatic or mildly symptomatic. At the end of the observational year, the overall data demonstrate (Table 3) a Significant increase of new diagnoses of COPD (+65 cases), a good efficiency in recording the "smoke habit" data (88.7% versus 71.5% initial), and an increase in the number of spirometry prescribed. Another important point is the average age at diagnosis in patients selected in the study: 55.5 years. The BMI could be recorded in 76% of COPD patients (mean BMI: 27.5 ± 5.6). Almost all GPs who participated in the study considered that the additional workload was compatible with the everyday activity. During the follow-up period (01/11/2011 - 31/10/2012) pulmonary function tests were 280 and Piko 6 examinations were 100. According to the spirometry data before the interventional study, it was demonstrated that the request increased by over 150%. Another significant data obtained from the "270° COPD" study concerns the intervention on smoking habit; in fact, after more than one year by the end of the study, half of the patients with newly COPD diagnosed (stage I) persisted in smoking cessation.

Table 3: COPD 270° Project – Summary of the key data at the end of the study.

• 689 patients with COPD diagnosis (*vs.* 624) (p 0.05)
• Final prevalence of COPD: 5, 63% (*vs.* 5, 08%)
• 55.5 years the average age of patients at the COPD diagnosis
• 88, 7% of the patients with "smoking habit" reported on the electronic folder (*vs.* 71, 5%) (p 0.05)
• 36.4% of COPD are smokers (*vs.* 27.2% of the basal data); previous smokers: 33.8%; never smokers: 29.8%
• 42% of patients with spirometry prescribed (*vs.* 29.6%) (p 0.01)
• 32.8% of patients with FEV1 recorded on the electronic folder (*vs.* 17.1%) (p 0.01)

Discussion

There is evidence suggesting that many patients have first COPD diagnosis when their bronchial airway obstruction has progressed substantially or during an acute respiratory exacerbation [3,4]. Studies in primary care indicate that the percentage of newly diagnosed COPD patients with moderate-to-severe bronchial airway obstruction in primary care ranges from 43% (Scotland, Colorado) [13] to 70% (Greece) [4]. A United States managed care database analysis suggested that 31% were GOLD III or IV [14] whereas a study in China found that 86% were moderate to severe and 34% had >2 exacerbations the prior year [15]. Identifying subjects with undiagnosed COPD should set in motion effective medical treatment and improve short and long-term health outcomes. In this context the development of a screening method for identifying patients with undiagnosed, clinically significant COPD in primary care is mandatory. In fact, today again many cases of COPD are diagnosed only after significant loss of lung function or during exacerbations. Furthermore, the interaction between GPs and pulmonologists specialists is still suboptimal in many countries. Some studies have also emphasized that the active involvement of GPs in COPD screening programs can provide tangible and meaningful results [5,6,11,13,16,17].

The Italian Project "COPD 270°" shows that the main problems encountered in the approach to the diagnosis of COPD are solved within the framework of primary care medicine with "opportunistic" interventions at very low cost. Our experience, restricted to a limited

number of GPs and performed in a limited geographic area, definitely needs to be confirmed and further studies, but appears concretely highlight the immense potential of primary care medicine in the ability to respond to concrete problems.

Conclusion

This study showed a greater awareness on the part of GPs of the problem "COPD"; an increase in the number of diagnosed cases of COPD (many of them at an early stage of GOLD severity classification); and a productive professional synergy between GPs and pulmonologists. Another significant result obtained with the "270° COPD" study concerns the intervention on smoking: after more than one year by the end of the study, half of the patients with newly COPD diagnosis persisted in smoking cessation. This data may be able to be significantly linked to the persistence over time of the doctor-patient relationship that binds often for decades the patient and their doctor will mark the relationship, making it significantly more effective interventions repeated over time.

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Conflicts of interest: There are no conflicts of interest.

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