A combination of handheld spirometer device and questionnaire- A potential screening tool for early diagnosis of chronic obstructive pulmonary disease

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Abstract

Background: Many cases of chronic obstructive pulmonary disease (COPD) continue to be undiagnosed or misdiagnosed. Screening of these patients with spirometry may help in detecting airflow obstruction before the subject develops clinical symptoms. But it is neither feasible nor cost effective and cannot be applied to huge population in India. Therefore, a need for a simple and cost effective method to identify persons who might have the early stages of COPD is warranted. The present study was done:-

1. To identify the utility of COPD population screener (COPD-PS) questionnaire + COPD-6 Hand-held spirometer device (HSD) as a screening tool for early diagnosis of COPD.
2. To identify the sensitivity and specificity of COPD-PS and COPD-6 device, individually and when used in combination, in the diagnosis of COPD.

Methodology: This is a cross sectional observational study done using a questionnaire (COPD-PS) and Hand-held spirometer device (COPD-6) during the three months period from May to July 2018 in the department of Pulmonary Medicine in Nizams Institute of Medical Sciences (NIMS). This study was approved by our institution's ethics committee.

Results: Out of the 89 patients screened, 69 had COPD-PS score >/=5 and 52 had a COPD-6 (FEV_1/FVC_6) <0.75. 57.3% of the patients were screened positive using the screening tools (COPD PS + COPD 6). Out of these, 52% of the patients turned out to have FEV1/FVC<0.7 on spirometry demonstrating obstruction, thereby confirming a diagnosis of COPD. When COPD-PS score alone has been used as a screening tool, the sensitivity was 100% and specificity was 47%. However when COPD-PS and COPD-6 device were used together, the sensitivity was 97.8% and specificity was 79.1%, showing a significant improvement in specificity and retained a high sensitivity (97.8%).

Conclusions: The combination of COPD-PS and COPD-6 is highly effective in early detection of undiagnosed airway obstruction in COPD and can guide effectively in subjecting the high risk patients to spirometry for confirming the diagnosis of COPD.

Keywords: Chronic obstructive pulmonary disease (COPD); Spirometry; Questionnaire; Screening tool.

Introduction

Chronic obstructive pulmonary disease (COPD) is the 4th leading cause of death [1] and the 13th leading cause of burden of diseases worldwide with an increase projected over in the next decade. COPD affects nearly 400 million people worldwide and its prevalence in India is 15 million [2]. Many cases are often diagnosed late, owing to patient ignorance as the symptoms like exertional dyspnea, increased sputum production, and chronic cough are considered to be part of normal aging and smoking [3]. Most of the COPD patients have history of cigarette smoking for a period of time before their diagnosis gets established. Buffels et al., [4] showed that the screening of smokers and ex-smokers revealed a prevalence of 4%–18% in individuals aged 35–70 years. Similarly, a study by Coultas et al., [5] revealed that subjects with undiagnosed airflow obstruction had a higher prevalence of smoking (82.3%) than those subjects with no airflow obstruction (54.2%).

Demonstration of airflow obstruction by spirometry (FEV1/FVC<0.7) is essential in making a definitive clinical diagnosis of COPD, as suggested by the GOLD committee [1]. Screening of patients with spirometry may help in detecting airflow obstruction before the subject develops clinical symptoms [6]. But it is neither feasible nor cost-effective and cannot be applied to the large population in India [2]. Early diagnosis of COPD may improve the quality of life by reducing symptoms and by preventing the progression of the disease. Once the diagnosis gets delayed, mortality and morbidity increases along with a huge burden of cost both on the patient and the country [7]. Therefore, a need for a simple and most cost-effective method to identify patients in early stages of COPD is the need of the hour.

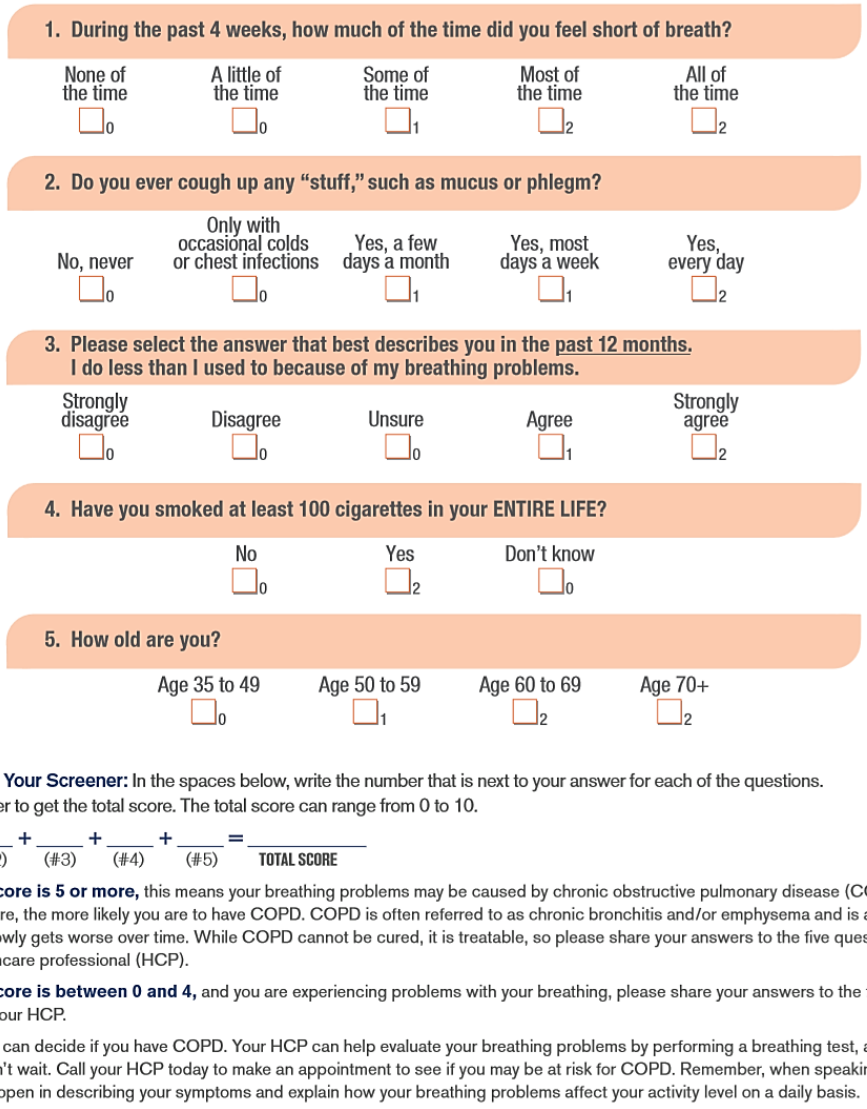
A recent multicenter, cluster-randomized study (SEARCH1) involving 8,770 volunteers has shown that dual-combination assessment using questionnaire screening and Handheld spirometer device **(**HSD) offered better COPD detection than the use of either method in isolation [8]. Several screening tools like COPD population screener (COPD-PS) questionnaire, HSD (COPD-6 device), International Primary care Airways Guidelines (IPAG) questionnaire, PIKO-6 (Hand held pocket spirometer) are available [9]. A study by Fernando J. Martinez et al, stressed the need to carry out a simple, self administered and self scored screening of patients at risk of COPD in primary care centers to fight the under diagnosis [10]. This study is being conducted to find out the utility of these screening tools in making an early diagnosis of COPD. Our study aims at identifying the utility of COPD-PS and HSD (COPD-6 device) as a rapid and cost effective screening tool for screening undiagnosed COPD. This tool could also assist physicians in identifying those individuals who would need spirometric assessment to confirm the diagnosis of COPD. The present study was done:-

1. To identify the utility of COPD-PS questionnaire + COPD-6(HSD) in screening symptomatic smokers (current and ex smokers) for early diagnosis of COPD.
2. To identify the sensitivity and specificity of COPD-PS and COPD-6 device, individually and when used in combination, in the diagnosis of COPD.
3. And comparison of these results with the gold standard spirometry for confirmation of diagnosis of COPD.

Materials and Methods

This is a cross sectional observational study done using a questionnaire (COPD-PS) and Hand-held spirometer device (COPD-6) during the three months period from May to July 2018 in the department of Pulmonary Medicine in Nizams Institute of Medical Sciences (NIMS). This study was approved by our institution's ethics committee. A written informed consent was obtained from study subjects.

The COPD Population Screener (COPD-PS™; Quality Metric Incorporated, Lincoln, Rhode Island, USA) is a validated, self-scored, 5-item questionnaire, used to identify patients at risk for COPD (Figure 1). It includes three questions (dyspnea, sputum production, and activity limitation) related to COPD and questions regarding smoking and age. It can be used as a first-level screener in diagnosing airflow obstruction reliably.



1. During the past 4 weeks, how much of the time did you feel short of breath?

None of the time ☐0 | A little of the time ☐0 | Some of the time ☐1 | Most of the time ☐2 | All of the time ☐2

2. Do you ever cough up any "stuff," such as mucus or phlegm?

No, never ☐0 | Only with occasional colds or chest infections ☐0 | Yes, a few days a month ☐1 | Yes, most days a week ☐1 | Yes, every day ☐2

3. Please select the answer that best describes you in the past 12 months. I do less than I used to because of my breathing problems.

Strongly disagree ☐0 | Disagree ☐0 | Unsure ☐0 | Agree ☐1 | Strongly agree ☐2

4. Have you smoked at least 100 cigarettes in your ENTIRE LIFE?

No ☐0 | Yes ☐2 | Don't know ☐0

5. How old are you?

Age 35 to 49 ☐0 | Age 50 to 59 ☐1 | Age 60 to 69 ☐2 | Age 70+ ☐2

How to Score Your Screener: In the spaces below, write the number that is next to your answer for each of the questions. Add the number to get the total score. The total score can range from 0 to 10.

_____ (#1) + ____ (#2) + ____ (#3) + ____ (#4) + ____ (#5) = _____ TOTAL SCORE

If your total score is 5 or more, this means your breathing problems may be caused by chronic obstructive pulmonary disease (COPD). The higher your score, the more likely you are to have COPD. COPD is often referred to as chronic bronchitis and/or emphysema and is a serious lung disease that slowly gets worse over time. While COPD cannot be cured, it is treatable, so please share your answers to the five question screener with your healthcare professional (HCP).

If your total score is between 0 and 4, and you are experiencing problems with your breathing, please share your answers to the five-question screener with your HCP.

Only your HCP can decide if you have COPD. Your HCP can help evaluate your breathing problems by performing a breathing test, also known as spirometry. Don't wait. Call your HCP today to make an appointment to see if you may be at risk for COPD. Remember, when speaking to your HCP, be honest and open in describing your symptoms and explain how your breathing problems affect your activity level on a daily basis.

Fig. 1

Adapted with permission from COPD: Journal of Chronic Obstructive Pulmonary Disease. Development and initial validation of a self-scored COPD Population Screener questionnaire (COPD-PS). [10]

COPD-6 (Fig. 2) is a small portable electronic device measuring 11.3 cm high, 6.3 cm wide and 4.5 cm thick. It is powered by two disposable batteries and weighs 55gram. COPD- 6 device is used to perform 6 second spirometry test which measure FEV1, FEV6 and the FEV1/FEV6. FEV1/FEV6 ratio can be used as an alternative to

FEV1/FVC, which involves performing a prolonged forced vital capacity maneuver (FVC). It is easier to use and requires no special training. The maneuver performed is similar to that of a spirometry. The patient takes a deep breath, then will insert the mouthpiece into the mouth and exhale vigorously and continuously for six seconds. The device emits a beep after 6 seconds to indicate that the patient can stop the maneuver. The cut-off point for the FEV1/FEV6 quotient is established between 0.75-0.80 [11]. This study considers FEV1/FEV6<0.75 as the cutoff. While FEV1/FEV6 greater than this value rules out obstruction with acceptable confidence, a lower result is an indication for a conventional spirometry study to confirm the diagnosis of COPD.

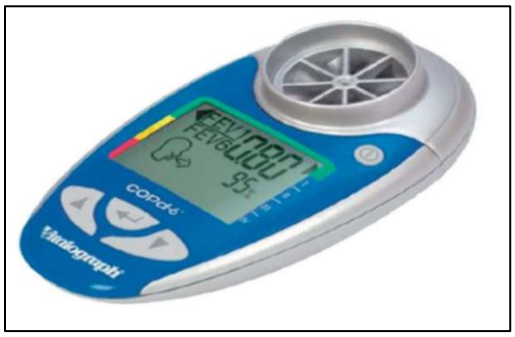


Fig. 2: COPD-6 device; Model 4000, Vitalograph

Patient Recruitment Procedure

All adult patients >35 years of age visiting outpatient department of Pulmonary Medicine in Nizams Institute of Medical Sciences (NIMS) during the study period and fulfilling the inclusion criteria will be included in the study after obtaining informed consent.

Inclusion Criteria

1. Age > 35 years
2. Are smokers or ex-smokers

Exclusion Criteria

1. Pregnancy
2. Previous medical diagnosis of COPD or any other respiratory disease
3. If they had been prescribed an inhaler (such as a bronchodilator and/or glucocorticoid).

Patients >35years of age who are smokers and ex-smokers are screened for potentially undiagnosed COPD using a validated five-item questionnaire (COPD-PS) and HSD (COPD-6 device; Model 4000, Vitalograph). Any person who smokes tobacco product, either daily or occasionally is defined as a smoker according to World Health Organization (WHO) smoking and tobacco use policy. Before performing routine spirometry, patients were subjected to COPD-PS questionnaire, and then were asked to perform the forced expiratory maneuver using the HSD. HSDs use the ratio of FEV1/FEV6 instead of the diagnostic ratio (FEV1/FVC) in detecting the airflow limitation of patient. The highest FEV1 and FEV6 values were independently selected from the three available measurements and used for analysis.

A COPD PS score of ≥ 5 and post bronchodilator FEV1/FEV6 <0.75 are highly suggestive of COPD. These values will be compared with post bronchodilatorFEV1/FVC ratio obtained from the gold standard spirometry. Combined sensitivity and specificity were calculated for a COPD-PS questionnaire and the 6-second spirometry results. Results will be analyzed by SPSS® software for sensitivity, specificity, positive predictive value, negative predictive value and chi square test. A P value of<0.05 is considered statistically significant.

Results

A total of 93 patients were screened in the present study, out of which 4 patients could not perform spirometry and COPD-6. So, 89 patients were included in the analysis. A summary of the results and comparison were presented in the following tables (Tables 1-6). Out of the 89 patients included, 83 were males (93%) and 6 were females (7%). Mean age of the population was 60.3 years. 21(23.6%) of them were current smokers and 68 (76.4%) were ex-smokers. Mean FEV1 % was 68.18+/-24 and mean FEV1/FVC was 0.67+/-0.14. Out of the 89 patients screened, 69 (77%) had COPD-PS score >/=5 and 52 (58%) had a COPD-6 (FEV_1/FVC_6) <0.75. 51 out of 89 (57.3%) screened positive using the screening tool (COPD PS + COPD-6). 47(52%) of the 89 patients turned out to have FEV1/FVC<0.7 on spirometry demonstrating obstruction, thereby confirming a diagnosis of COPD.

No. of patients screened	COPD-PS>/=5	COPD-6<0.75	Screening positive (COPD-PS>/=5 + COPD-6<0.75)	Spirometry (FEV1/FVC<0.7)
89	69(77.5%)	52(58.4%)	51 (57.3%)	47 (52.8%)

When COPD-PS score alone was used as a screening tool, the sensitivity was 100% and specificity was 47% (47/69 screened patients had FEV1/FVC <0.7). However when both COPD-PS and COPD-6 device were used together, (ie a COPD-PS score >/= 5 and COPD-6 score <0.75, the sensitivity was 97.8% and specificity was 79.1% (46 out of 51 had FEV1/FVC<0.7) showing a significant improvement in specificity and retained a high sensitivity (97.8%). When COPD-PS and COPD-6 in combination is used as a screening tool, the positive predictive value was 90.19 and negative predictive value was 95.Patients screened positive(COPD-PS >/= 5 and COPD-6 <0.75), had an FEV_1% of 52+/-13.32 which is quite low, as compared to an FEV1% of 89.89+/- 15.83 among those screened negative. Among those who screened positive mean age is eight years older than those screened negative. (63 years vs 55 years).

The following factors were observed in patients of COPD in our study.

1. Smoking history of >20 pack years: In this study, smoking for >20 pack years had a positive association with COPD and a low FEV_1% (48+/-14) (p value of 0.0002 and 0.0001 respectively). Out of the 25 patients who smoked for >20 pack years, 22 had COPD and were also screened positive with the screening tool.
2. Age: The current study showed that patients with COPD had a mean age of 63.5 years which is higher than those without COPD (56.8 years). The association between age and COPD is statistically significant, p=0.002.
3. Active smoking: 15% of the COPD patients (7/47) were actively smoking. The current study also identified an association between active smoking and COPD which is statistically significant (0.041). Male sex was associated with COPD-PS >/=5 (p=0.094) and current smoking was associated with COPD -6 <0.75(p=0.001).

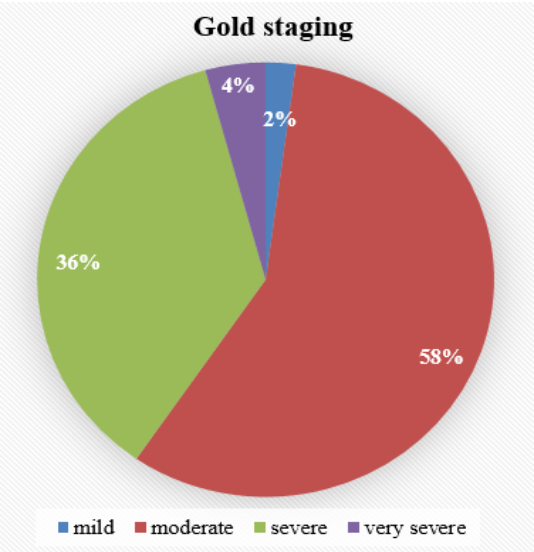


Fig. 3

Out of the 47 diagnosed as COPD on Gold staging, one had mild obstruction, 27(57%) had moderate obstruction, 17(36%) had severe and 2(4.25%) had very severe obstruction. Majority of them 93% (43) belonged to moderate to severe obstruction according to GOLD staging. (Fig. 3)

Tables: Comparison of study characteristics, COPD-PS score, FEV_1/FEV_6, FEV_1/FVC and smoking status

Table 1: Characteristics of the study population

	Mean ± Standard deviation
Age	60.3.6±10.44
COPD- PS	6.67±2.344
COPD-6 (FEV_1/FEV_6)	70.93±15.37
FEV_1/FVC	0.67±0.14
FEV_1	68.18±24.105
Sex	
Male	83(93.3%)
Female	6(6.7%)
Smoking	
Yes	21(23.6%)
No	68(76.4%)
COPD- PS	
<5	20(22.5%)
≥5	69(77.5%)
FEV_1/FVC	
<0.7	47(52.8%)
≥0.7	42(47.2%)
COPD- 6	
<0.75	52(58.4%)
≥0.75	37(41.6%)

Table 2: Comparison between COPD-PS score (normal score <5 vs ≥5)

		COPD-PS		
		<5	≥ 5	
Active smoking	Yes	7 (33.3%)	14 (66.7%)	Chi square=1.861
	No	13 (19.1%)	55 (80.9%)	P value=0.172
FEV_1/FVC	<0.7	0 (0%)	47 (100%)	Chi square=28.86
	≥0.7	20 (47.6%)	22 (52.4%)	P value=0.0001
FEV_1/FEV_6(COPD-6)	<0.75	1 (1.9%)	51 (98.1%)	Chi square=30.316 P
	≥0.75	19 (51.4%)	18 (48.6%)	value=0.0001
Mean FEV_1/FVC		0.82 ± 0.064	0.62± 0.13	P value = 0.0001
FEV_1 %		93.6 ±18.8%	60.8±20.17%	P value = 0.0001

Table 3: Comparison between FEV_1/FEV_6 ratio < 0.75 vs ≥ 0.75

		COPD-6		
		<0.75	≥0.75	
Smoking	Yes	6(28.6%)	15(71.4%)	Chi square=10.086 P value=0.001
	No	46(67.6%)	22(32.4%)	
FEV_1/FVC	<0.7	46(97.9%)	1(2.1%)	Chi square=63.798 P value=0.0001
	≥0.7	6(14.3%)	36(85.7%)	
COPD-PS	<5	1(5.0%)	19(95%)	Chi square=30.316 P value=0.0001
	≥5	51(73.9%)	18(21.6%)	
FEV_1/FVC		52(0.56±0.09)	37(0.81±0.07)	P value = 0.0001
FEV_1		52(52.15±13.23)	37(90.7±16.72)	P value = 0.0001

Table 4: Comparison of FEV_1/FVC <0.7 (COPD) vs FEV_1/FVC ≥0.7 (healthy population)

		FEV_1/FVC		
		<0.7	≥0.7	
Sex	Male	44(53.0%)	39(47.0%)	Chi square=0.02 P value=0.887
	Female	3(50.0%)	3(50.0%)	
COPD-PS	<5	0(0%)	20(100%)	Chi square=28.868 P value=0.0001
	≥5	47(68.1%)	22(31.9%)	
COPD- 6 (FEV_1/FEV_6)	<0.75	46(88.5%)	6(11.5%)	Chi square=63.798 P value=0.0001
	≥0.75	1(2.7%)	36(97.3%)	
Smoking	Yes	7(33.3%)	14(66.7%)	Chi square=4.183 P value=0.041
	No	40(58.8%)	28(41.2%)	
GOLD staging	Mild	1(100%)	0(0%)	
	Moderate	27(100%)	0(0%)	
	Severe	17(100%)	0(0%)	
	Very severe	2(100%)	0(0%)	
Age		47(63.51±8.52)	42(56.83±11.34)	P value=0.002
FEV_1		47(51.77±13.64)	42(86.55±19.58)	P value=0.0001
FEV_1/FVC		47(0.55±0.08)	42(0.8±0.07)	P value=0.0001

Table 5: Comparison of current smokers vs ex-smokers

		Smoking		
		Yes	**No**	
Sex	Male	21(25.3%)	62(74.7%)	Chi square=1.987 P value=0.159
	Female	0(0%)	6(100%)	
COPD-PS	<5	7(35%)	13(65%)	Chi square=1.86 P value=1.72
	≥5	14(20.3%)	55(79.7%)	
COPD-6 (FEV_1/FEV_6)	<0.75	6(11.5%)	46(88.5%)	Chi square=10.086 P value=0.001
	≥0.75	15(40.5%)	22(59.5%)	
FEV_1/FVC	<0.7	7(14.9%)	40(85.1%)	Chi square=4.183 P value=0.041
	≥0.7	14(33.3%)	28(66.7%)	
GOLD staging	Mild	0(0%)	1(100%)	
	Moderate	5(18.5%)	22(81.5%)	
	Severe	2(11.8%)	15(88.2%)	
	Very severe	0(0%)	2(100%)	
Age		21(53.14±8.314)	68(62.59±10.07)	P value=0.0001
FEV_1		21(80.29±20.35)	68(64.44±24.06)	P value=0.005
FEV_1/FVC		21(0.72±0.12)	68(0.65±0.15)	P value=0.038

Table 6: Comparison of patients with smoking history of ≤20 pack years >20 pack years

		Smoking		
		≤20 Pack years	**>20 Pack years**	
COPD- PS	<5	20(100%)	0(0%)	Chi square=10.077
	≥5	44(63.8%)	25(36.2%)	P value=0.002
COPD-6	<0.75	29(55.8%)	23(44.8%)	Chi square=16.133
(FEV_1/FEV_6)	≥0.75	35(96.4%)	2(5.4%)	P value=0.0001
FEV_1/FVC	<0.7	25(53.2%)	22(46.8%)	Chi square=17.276
	≥0.7	39(92.9%)	3(7.1%)	P value=0.0001
GOLD Staging	Mild	1(100%)	0(0%)	Chi square=10.096
	Moderate	19(70.4%)	8(29.6%)	P value=0. 018
	Severe	4(23.5%)	13(76.5%)	
	Very severe	1(50%)	1(50%)	

Discussion

Using the screening tool (COPD-PS ≥5 and COPD-6<0.75), our current study could identify 57% (51/89) as potentially undiagnosed COPD, which is very much higher than the studies published in the literature by Sichletidis et al., (10.4%) [9] and Chi Faisui et al., (8.4%) [12]. In a study by Tinkleman et al., up to 30% of smokers experienced undiagnosed COPD while undiagnosed COPD in the overall population is 10-20% [13]. In a case finding study, smokers aged 40-75 years with acute respiratory infection and with no previous diagnosis of respiratory disease yielded a 27% incidence of undiagnosed COPD [14]. Another study of undiagnosed COPD by Vandevoorde et al., found a 29.5% incidence (n=146) in active smokers aged 40–70 years who smoked at least 15 packs/year [15]. The reason for a higher percentage of positively screened people in our study is because the fact that the present study was performed in a tertiary care hospital unlike the other studies which were conducted in a primary care hospital. Most of the patients visiting the outpatient department at our hospital have been sensitized about their symptoms and smoking status and referred here by their primary care provider.

Out of the 89 patients screened, COPD-PS questionnaire could identify 69 patients (sensitivity 100% and specificity 47%). COPD-6 could identify 52 of 89. Combining both screening methods could identify 51 out of 89(57.3%) as potentially undiagnosed COPD. Out of them, 46 were confirmed to have COPD by the gold standard spirometry (FEV_1/FVC<0.7) (sensitivity=97.8%, specificity=79.2%) showing a significant improvement in specificity and retained a high sensitivity (97.8%). Similar findings were observed in a study conducted by Yawn et al., which stated that dual assessment using a questionnaire and hand held spirometer device may provide limited additional advantage [16]. When COPD-PS and COPD-6 in combination is used as a screening tool in our study, the positive predictive value was 90.19 and negative predictive value was 95. A similar study by Sichletidis et al., using International Primary Care Airways Guidelines (IPAG) questionnaire and PiKo-6(FEV_1/FVC_6<0.75) yielded a positive predictive value of 82% [9].

Pre-selection with a questionnaire may reduce costs, therefore subjecting a more targeted group of patients to undergo testing with spirometry. Many trials have advocated different types of screening questionnaires [9,10,17-20] followed by spirometry to confirm the diagnosis of airway obstruction. A recent trial also used a similar two-step approach with an IPAG questionnaire and PiKo-6, [9] instead of the COPD-PS and COPD-6 which was used in our present study. In the former study, a positive IPAG questionnaire for possible COPD (>17 points) was obtained in 594 (55.1%) subjects while our COPD-PS questionnaire yielded a result of 77.5% (scores >5). With PiKo-6 (a similar device to COPD-6), 139 (12.9%) subjects fulfilled the criteria for possible COPD (FEV1/FEV6 <0.7), while our present study with COPD-6 HSD showed 58.4% (52/89) as possible COPD. When both COPD-PS questionnaire and COPD-6 device were used in combination, our study showed 57.3% (51/89) of total patients as potentially undiagnosed COPD.

A cross-sectional study in male smokers aged 40–65 years revealed an airway obstruction in approximately 29.9% of cases [21]. This study used a questionnaire followed by spirometry for subjects without previous diagnosis of COPD.A local pilot cross-sectional study conducted in Malaysia by Ching et al., [22] using a similar handheld spirometer managed to detect airway obstruction in 10.6% of the patients. Further testing with the diagnostic spirometry in the similar study confirmed the diagnosis of COPD in 6% of the cases. Similarly in our study, screening questionnaire plus HSD showed that 57.3%had possible COPD and spirometry confirmed 51.7% as COPD. This shows that a questionnaire plus HSD is highly effective in making a targeted use of spirometry to diagnose COPD.

Findings from a Korean trial of COPD screening suggest that advanced age increases the number of undiagnosed airway obstructions [23]. The authors found that the association between potentially undiagnosed airflow obstruction and age was particularly strong, with prevalence increasing from 4.6% in those aged 40–49 years to 40% in those aged 60–69 years. Consistent with these findings, our study yielded the mean age of COPD patients as 63.5+/-8.32, while that of patients without COPD was 56.8+/-7.3. Also mean age for those who smoked for>20 years was 64.4 years. Our study also showed a strong association between age and COPD (p=0.002). Similar findings were noted in a study

conducted by Eva Balcells et al., [24] which showed that mean age at which COPD got diagnosed was at 68 years.

Utility of the Screening Tool

In our study 15% (7/47) of COPD patients are actively smoking at the time of diagnosis. Smoking history for more than 20 pack years is associated with COPD and low FEV_1 (FEV_1<50%) (p value 0.0001 and 0.018 respectively). Analysis of exacerbations in 2138 patients enrolled in the ECLIPSE study demonstrated more severe exacerbations and hospitalizations in association with increased severity of COPD disease [25]. Overall, 22% of patients with stage 2 disease, 33% with stage 3 and 47% with stage 4 had frequent exacerbations in the first year of follow-up. Mark Miravitiles et al., [26] reported that patients with stage 3 disease treated according to GOLD guidelines had significantly higher treatment costs. So to reduce costs of treatment and risk of exacerbations, smokers have to be sensitized early in the course of their disease which is much before the time of their first presentation to the hospital. This can be achieved only by using a screening tool. Such patients can be screened earlier in the course of disease and can be advised to quit smoking which would help in reducing the rate of progression of COPD.

Limitations

This study was performed in a tertiary care hospital where most of the patients have been sensitized about their symptoms and smoking status and referred here by their primary care providers. And so the high percentage of detection of COPD by the screening tools and HSD was achieved. The results however cannot be applicable to the general population and in young smokers of less than 25 years of age. Another limitation was that we did not screen non smokers and younger age groups in our study. Further research of screening patients with potential bio mass fuel exposure, recurrent respiratory tract infections including old tuberculosis sequelae is needed as these are considered to be the common neglected causes of COPD leading to increased morbidity and mortality.

Conclusions

The combination of screening questionnaire (COPD-PS) and hand held spirometer (COPD-6) is highly effective in early detection of undiagnosed airway obstruction in COPD patients. Therefore this combination method can facilitate and subject the high risk people in resource free settings to spirometry for confirming the diagnosis of COPD.

Conflicts of Interests: None declared.

Acknowledgements: Nil.

References

1. Vogelmeier CF, Criner GJ, Martinez FJ, Anzueto A, Barnes PJ, Bourbeau J et al. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Lung Disease 2017 Report: GOLD Executive Summary. *Eur Respir J* 2017;49(3).
2. Gupta D, Agarwal R, Aggarwal AN, Maturu VN, Dhooria S, Prasad KT et al. Guidelines for diagnosis and management of chronic obstructive pulmonary disease: Joint ICS/NCCP (I) recommendations. *Lung India* 2013;30(3):228-67.
3. Albers F, Shaikh A, Iqbal A. Design, rationale, and baseline demographics of SEARCH I: a prospective cluster-randomized study. *Int J Chron Obstruct Pulmon Dis* 2012;7:437-445.
4. Buffels J, Degryse J, Heyrman J, Decramer M, DIDASCO Study. Office spirometry significantly improves early detection of COPD in general practice: the DIDASCO Study. *Chest* 2004;125(4):1394–1399.
5. Coultas DB, Mapel D, Gagnon R, Lydick E. The health impact of undiagnosed airflow obstruction in a national sample of United States adults. *Am J Respir Crit Care Med* 2001;164(3):372–377.
6. Schermer TR, Jacobs JE, Chavannes NH. Validity of spirometric testing in a general practice population of patients with chronic obstructive pulmonary disease (COPD). *Thorax* 2003;58(10):861–866.
7. Sui CF, Ming LC, Neoh CF, Ibrahim B. Vital Q Plus: a potential screening tool for early diagnosis of COPD. *Int J Chron Obstruct Pulmon Dis* 2015;10:1613-1622.
8. Yawn BP, Duvall K, Peabody J. The impact of screening tools on diagnosis of chronic obstructive pulmonary disease in primary care. *Am J Prev Med* 2014;47(5):563–575.
9. Sichletidis L, Spyratos D, Papaioannou M. A combination of the IPAG questionnaire and PiKo-6® flow meter is a valuable screening tool for COPD in the primary care setting. *Prim Care Respir J* 2011;20(2):184–189.
10. Martinez FJ, Raczek AE, Seifer FD. COPD-PS Clinician Working Group. Development and initial validation of a self-scored COPD Population Screener Questionnaire (COPD-PS). *COPD* 2008;5(2):85–95.
11. Cristina Represas Represas, Maribel Botana Rial, Virginia Leiro Fernández. Assessment of the Portable COPD-6 Device for Detecting Obstructive Airway Diseases. *Arch Bronconeumol* 2010;46(8):426-432.
12. Sui CF, Ming LC, Neoh CF, Ibrahim B. Vital Q Plus: a potential screening tool for early diagnosis of COPD. *Int J Chron Obstruct Pulmon Dis* 2015;10:1613-1622.
13. Tinkelman DG, Price D, Nordyke RJ, Halbert RJ. COPD screening efforts in primary care: what is the yield? *Prim Care Respir J* 2007;16(1):41-48.
14. Sandelowsky H, Ställberg B, Nager A, Hasselström J. The prevalence of undiagnosed chronic obstructive pulmonary disease in a primary care population with respiratory tract infections - a case finding study. *BMC Fam Pract* 2011;12:122.
15. Vandevoorde J, Verbanck S, Schuermans D, Kartounian J, Vincken W. FEV1/FEV6 and FEV6 as an alternative for FEV1/FVC and FVC in the spirometric detection of airway obstruction and restriction. *Chest* 2005;127(5):1560-1564.
16. Yawn BP, Duvall K, Peabody J, Albers F, Iqbal A, Paden H. The impact of screening tools on diagnosis of chronic obstructive pulmonary disease in primary care. *Am J Prev Med* 2014;47(5):563-575.
17. Kotz D, Nelemans P, van Schayck CP, Wesseling GJ. External validation of a COPD diagnostic questionnaire. *Eur Respir J* 2008;31(2):298-303.
18. Freeman D, Nordyke RJ, Isonaka S, Nonikov DV, Maroni JM, Price D et al. Questions for COPD diagnostic screening in a primary care setting. *Respir Med* 2005;99(10):1311-1318.
19. Price DB, Tinkelman DG, Halbert RJ, Nordyke RJ, Isonaka S, Nonikov D. Symptom-based questionnaire for identifying COPD in smokers. *Respiration* 2006;73(3):285-295.

20. Levy ML, Fletcher M, Price DB, Hausen T, Halbert RJ, Yawn BP. International Primary Care Respiratory Group (IPCRG) Guidelines: diagnosis of respiratory diseases in primary care. *Prim Care Respir J* 2006;15(1):20-34.
21. Geijer RM, Sachs AP, Hoes AW, Salomé PL, Lammers JW, Verheij TJ. Prevalence of undetected persistent airflow obstruction in male smokers 40-65 years old. *Fam Pract* 2005;22(5):485-489.
22. Ching SM, Pang YK, Price D, Cheong AT, Lee PY, Irmi I. Detection of airflow limitation using a handheld spirometer in a primary care setting. *Respirol* 2014;19(5):689-693.
23. Shin C, Lee S, Abbott RD, Kim JH, Lee SY, In KH. Respiratory symptoms and undiagnosed airflow obstruction in middle-aged adults: the Korean Health and Genome Study. *Chest* 2004;126(4):1234-1240.
24. Balcells E, Antó JM, Gea J, Gómez FP, Rodríguez E, Marin A. Characteristics of patients admitted for the first time for COPD exacerbation. *Respir Med* 2009;103(9):1293-1302.
25. Vestbo J, Anderson W, Coxson HO, Crim C, Dawber F, Edwards L et al. Evaluation of COPD Longitudinally to Identify Predictive Surrogate End-points (ECLIPSE). *Eur Respir J* 2008;31(4):869-873.
26. Miravitlles M, Sicras A, Crespo C, Cuesta M, Brosa M, Galera J et al. Costs of chronic obstructive pulmonary disease in relation to compliance with guidelines: a study in the primary care setting. *Ther Adv Respir Dis* 2013;7(3):139-150.

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