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# ผลการตรวจ Spirometry และปัจจัยที่มีความสัมพันธ์กับคุณภาพการทดสอบ Spirometry ในผู้ป่วยโรคปอดอุดกั้นเรื้อรัง โรงพยาบาลศรีสะเกษ

กฤษณา ติยวรนันท์
*กลุ่มงานอายุรกรรม โรงพยาบาลศรีสะเกษ*

# Spirometry Test Results and Factors Associated with Quality of Spirometry Test in Patients with Chronic Obstructive Pulmonary Disease (COPD) at Sisaket Hospital

Krisana Tiyaworanan
*Department of Medicine, Sisaket Hospital*

**หลักการและวัตถุประสงค์**: การวินิจฉัยโรคปอดอุดกั้นเรื้อรังที่ถูกต้องมีความสำคัญต่อการรักษา ในประเทศไทยการวินิจฉัยโรคปอดอุดกั้นเรื้อรังมักอาศัยอาการทางคลินิกเป็นหลัก เนื่องจากการตรวจ Spirometry ไม่สามารถทำได้ในทุกโรงพยาบาล แต่ตามเกณฑ์การวินิจฉัยโรคปอดอุดกั้นเรื้อรังจำเป็นต้องอาศัยผลการตรวจ Spirometry การศึกษานี้จึงมีวัตถุประสงค์เพื่อศึกษาผลการตรวจ Spirometry และปัจจัยที่มีความสัมพันธ์กับคุณภาพการทดสอบ Spirometry ในผู้ป่วยที่ได้รับการวินิจฉัยจากอาการทางคลินิกว่าเป็นโรคปอดอุดกั้นเรื้อรัง

**วิธีการศึกษา**: เป็นการศึกษาแบบเป็น Observational study โดยผู้ป่วยที่ได้รับการวินิจฉัยว่าเป็นโรคปอดอุดกั้นเรื้อรังจะได้รับการประเมินโดยอาศัยแบบเก็บข้อมูลและได้รับการตรวจ Spirometry

**ผลการศึกษา**: มีผู้ป่วยเข้าร่วมการศึกษา 168 ราย เป็นเพศชาย 133 ราย หญิง 35 ราย อายุเฉลี่ย 68.3 ± 10.3 ปี มีประวัติสูบบุหรี่ร้อยละ 72 มีประวัติเคยเป็นวัณโรคปอด 59 ราย (ร้อยละ 35.1) มีโรคร่วมในกลุ่ม Metabolic syndrome และโรคหัวใจและหลอดเลือด 73 ราย (ร้อยละ 43.4) มีผลการตรวจ Spirometry ได้คุณภาพ 99 ราย (ร้อยละ 58.9) ในกลุ่มที่ผลการตรวจได้คุณภาพพบว่าเข้าได้กับโรคปอดอุดกั้นเรื้อรัง 34 ราย (ร้อยละ 34.3) และพบว่า อายุที่เพิ่มขึ้น, คะแนน mMRC ≥ 2 หรือ CAT score ≥ 10 มีความสัมพันธ์กับคุณภาพการทดสอบ Spirometry อย่างมีนัยสำคัญทางสถิติ

**Background and Objective**: Effective treatments of COPD rely on the accurate diagnosis. In Thailand COPD is mainly diagnosed by observing clinical manifestations because spirometry test cannot be performed in all hospitals. However, accurate COPD diagnosis needs spirometry test. The objective of this study was to evaluate spirometry test results and factors associated with quality of spirometry test in patients diagnosed with COPD from clinical manifestations.

**Methods**: An observational study was applied in this study for assessing patients diagnosed with COPD by using a case record form and performing spirometry test.

**Results**: There were 168 patients involved in the study, 133 males, 35 females; mean age 68.3 ± 10.3 years. Seventy-two percent of patients had history of smoking, 59 patients had undergone pulmonary tuberculosis (35.1%), 73 patients (43.4%) experienced comorbidities belonging to metabolic syndrome and cardiovascular diseases. Ninety-nine patients had valid spirometry test results (58.9%). Those with valid ones demonstrated that 34 patients met GOLD criterion for COPD diagnosis (34.3%). Increased age, mMRC dyspnea scale ≥ 2 or CAT score ≥ 10 had statistically significant association with quality of spirometry test.

**Conclusion**: There were 58.9% of patients had valid spirometry test results. Those with valid ones demonstrated that 34.3% met GOLD criterion for COPD diagnosis.

**สรุป**: จากการศึกษาพบว่าผลการตรวจ Spirometry ได้คุณภาพร้อยละ 58.9 ในกลุ่มที่ผลการตรวจได้คุณภาพพบว่าเข้าได้กับโรคปอดอุดกั้นเรื้อรังร้อยละ 34.3 โดยปัจจัยที่มีความสัมพันธ์กับคุณภาพการทดสอบ Spirometry ได้แก่ อายุที่เพิ่มขึ้น, คะแนน mMRC ≥ 2 หรือ CAT score ≥ 10

**คำสำคัญ**: โรคปอดอุดกั้นเรื้อรัง, การตรวจ Spirometry, คุณภาพการทดสอบ Spirometry

Factors associated with quality of spirometry test were increased age, and mMRC dyspnea scale ≥ 2 or CAT score ≥ 10.

**Keywords:** COPD, spirometry test, quality of spirometry test

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### Introduction

Chronic obstructive pulmonary disease (COPD) remains a major public health problem and becomes the fourth leading cause of death worldwide[1]. Also, it is the crucial problem in Thailand. According to the report released by National Health Security Office, it was found that there were 1.5 million Thai people suffering from COPD[2].

Effective treatments rely on the accurate diagnosis. However, there remain certain problems on diagnosis in general and regional hospitals in Thailand due to the diagnosis mainly made by observing clinical manifestations such as chronic cough, chronic progressive dyspnea, productive sputum with history of having risk factors without performing spirometry to ensure an accurate diagnosis. Moreover, in Thailand, little is known concerning the association between the diagnosis of COPD through observing clinical manifestations and spirometry test results and factors associated with quality of spirometry test. As a result, this study was conducted to evaluate spirometry test results in patients diagnosed with COPD from observing clinical manifestations and assess factors associated with quality of spirometry test.

## Methods

An observational study was applied in this study. Patients with COPD (ICD-10: J44) attending to COPD clinic and taking spirometry test from August 2014 to July 2015 made up of all the population in this study. The data collection was done using a case record form and collecting spirometry test results. Calculation of sample size was done by using equation: Sample size $n$ = $[DEFF*Np(1-p)]/ [(d^2/Z^2_{1-\alpha/2}*(N-1)+p*(1-p)]$, N was total COPD patients in Sisaket Hospital (567 patients), p was 26% according to previous study from Lindstrom, et al[3]., which found prevalence of airflow limitation from spirometry test in patients clinically diagnosed with chronic bronchitis which was 26%. The calculated sample size with 90% confidence interval was 153 patients. This study had been approved by Sisaket Hospital Research Ethics Committee.

Spirometry test results were considered valid based on acceptability criteria and repeatability criteria[4]. Patients initially took in a very deep breath and blew out correctly according to acceptability criteria. That is, a test is acceptable if all the following apply; maximal expiratory effort was maintained throughout the test, patients did not cough or suspend during the first second of the test, forced expiration maintained for at least 6 seconds/or there was plateau for at least one second. Then, the entire process was repeated to get at least three valid test results. The difference between the highest and second-highest values for $FEV_1$ and FVC in these three tests was < 150 mL according to repeatability criteria.

According to the GOLD criteria[5], the diagnosis for COPD is based on the post-bronchodilator $FEV_1$/FVC < 0.7 as well as the age > 40 years with history of the symptoms, progressive dyspnea, chronic cough, chronic sptum production, and the history of having risk factors, which is the tobacco smoking and exposure

to environmental air pollution. While the diagnosis of asthma is based on the pre-bronchodilator $FEV_1$/FVC less than usual (< 0.7) and $FEV_1$ increases by more than 12% and 200 mL after inhaling a bronchodilator[4]. Small airway disease is suggested by $FEF_{25-75\%}$ < 65% predicted with normal pre-bronchodilator $FEV_1$, FVC and $FEV_1$/FVC[4]. A restrictive ventilatory defect is defined according to a normal pre-bronchodilator $FEV_1$/FVC and corrected FVC < 80% predicted [4], which is calculated from FVC (% predicted) + (70-% FEV1/FVC). The diagnosis of obstructive and restrictive ventilatory defect is based on a prebronchodilator $FEV_1$/FVC < 0.7 and corrected FVC < 80% predicted[4]

**Inclusion criteria:** Patients aged 40 years or older diagnosed with COPD attending to COPD clinic and performing spirometry test from August 2014 to July 2015

**Exclusion criteria:**

Patients with contraindications to perform spirometry test, with active respiratory tuberculosis and with lung cancer

**Statistics in Research:** Calculation of mean, median, standard deviation and calculating the association by performing Chi-Square Test using SPSS version 20

## Results

There were 168 patients meeting inclusion criteria (133 male, 35 female; mean age 68.3 ± 10.3 years). Patients' demographic data are shown in Table 1. There were 121 patients (72%) who had history of smoking (109 previous smokingand 12 current smoking).

**Comorbidities:** There were 73 patients (43.4%) had comorbidities belonging to metabolic syndrome and cardiovascular diseases. Moreover, there were 59 patients with previous pulmonary tuberculosis history (35.1%).

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**Table 1** Patients' demographic data

| Characteristics | Number of patients N (%) |
|---|---|
| **Age (year)** | |
| 42-59 | 33 (19.6) |
| 60-69 | 50 (29.8) |
| 70-79 | 66 (39.3) |
| 80-89 | 19 (11.3) |
| Mean 68.3 ± 10.3 | |
| **Sex** | |
| Male | 133 (79.2) |
| Female | 35 (20.8) |
| **Risk factors** | |
| Previous smoking | 109 (64.9) |
| Current smoking | 12 (7.1) |
| Living with smokers | 50 (29.8) |
| Exposure to air pollution | 71 (42.3) |
| Non smoking but living with smokers | 16 (9.5) |
| Non smoking but exposure to air pollution | 18 (10.7) |
| No risk factors | 21 (12.5) |
| **Comorbidities** | |
| Hypertension | 56 (33.3) |
| Obesity (BMI ≥ 25 $Kg/m^2$) | 22 (13.1) |
| Diabetes mellitus | 10 (6) |
| Coronary artery disease | 10 (6) |
| Dyslipidemia | 8 (4.8) |
| Cerebral infarction | 5 (3) |
| Atrial fibrillation | 3 (1.8) |

**Severity of COPD:** The mean CAT score was 11.3 ± 7.4, median mMRC dyspnea scale was 1, median frequency of exacerbation led to ER visit was 1 time/year, and median exacerbation led to hospital admission was 1 time/year.

**Spirometry test results:** The spirometry test results are shown in Table 2. Of the patients involved in the study, 99 (58.9%) had valid spirometry test results according to acceptability criteria and repeatability criteria[4]. Those with valid ones demonstrated that among them 34 patients met GOLD criterion for COPD

diagnosis[5] (34.3%); most patients were categorized into GOLD 2. It was also found that 8 patients (8.1%) whose test results found obstructive and restrictive ventilatory defect had former history of pulmonary tuberculosis together with smoking history or exposure to air pollution.

Table 2 Spirometry test results

When determining the association between gender, age group, smoking history, mMRC dyspnea scale ≥ 2, CAT score ≥ 10 and the invalid test results in patients with invalid ones demonstrated that there was statistically significant association in increased age, mMRC dyspnea scale ≥ 2 or CAT score ≥ 10 and the invalid test results as shown in Table 3, 4 and 5.

When determining the association between former history of pulmonary tuberculosis and Body Mass Index (BMI) value in patients taking spirometry showing the presence of obstructive and restrictive ventilatory defect or restrictive ventilatory defect found that there was statistically significant association in former history of pulmonary tuberculosis and these spirometry test results (p = 0.013) as shown in Table 6.

**Table 2** Spirometry test results

| Spirometry test results | Number of patients N (%) |
|---|---|
| 1.Invalid | 69 (41.1) |
| 2.Valid | 99 (58.9) |
| 2.1 Obstructive ventilatory defect* | 48 (48.5) |
| 2.1.1 Post bronchodilator $FEV_1/FVC < 0.7$ | 43 (43.4) |
| Onset at age over 40 years old with history of exposure to tobacco smoke or air pollution (COPD) | 34 (34.3) |
| Onset at age less than 40 years old or no history of exposure to tobacco smoke and air pollution (Asthma with fixed obstruction) | 9 (9.1) |
| 2.1.2 Post bronchodilator $FEV_1/FVC \geq 0.7$ | 5 (5.1) |
| Positive bronchodilator reversibility test** (Asthma) | 2 (2) |
| Negative bronchodilator reversibility test | 3 (3) |
| 2.2 Obstructive and restrictive ventilatory defect | 22 (22.2) |
| 2.2.1 History of previous pulmonary TB and exposure to tobacco smoke or air pollution | 8 (8.1) |
| 2.3 Restrictive ventilatory defect | 11 (11.1) |
| 2.4 Small airway disease | 7 (7.1) |
| 2.5 Normal | 11 (11.1) |

*Pre bronchodilator $FEV_1/FVC < 0.7$ [4]

**Post bronchodilator $FEV_1$ increase > 12% and > 200 mL[4]

**Table 3** The association between spirometry test results and age groups

| Age groups (year) | 42-59 | 60-69 | 70-79 | 80-89 |
|---|---|---|---|---|
| Invalid test results (N) | 8 | 19 | 28 | 14 |
| Valid test results (N) | 25 | 31 | 38 | 5 |

p=0.006

**Table 4** The association between spirometry test results and mMRC dyspnea scale

| mMRC dyspnea scale | 0-1 | ≥ 2 |
|---|---|---|
| Invalid test results (N) | 48 | 21 |
| Valid test results (N) | 87 | 12 |

p=0.003

**Table 5** The association between spirometry test results and CAT score

| CAT score | < 10 | ≥ 10 |
|---|---|---|
| Invalid test results (N) | 26 | 43 |
| Valid test results (N) | 57 | 42 |

p=0.011

**Table 6** The association between spirometry test results showing the presence of obstructive and restrictive ventilatory defect or restrictive ventilatory defect and previous history of pulmonary tuberculosis

| Spirometry test results | Obstructive and restrictive ventilatory defect or restrictive ventilatory defect | Others |
|---|---|---|
| Previous history of pulmonary tuberculosis | 18 | 19 |
| No history of pulmonary tuberculosis | 15 | 47 |

p=0.013

**Treatments:** Patients were prescribed short acting bronchodilators (SABA or SABA/SAMA) including salbutamol inhaler, fenoterol/ipratropium bromide inhaler; inhaled corticosteroid (ICS) including budesonide; combination inhaled corticosteroid/ long-acting beta2-agonist ( ICS/LABA) such as salmeterol/fluticasone, formoterol/budesonide; long-acting muscarinic antagonist (LAMA) which is tiotropium; leukotriene receptor antagonist (LTRA) including montelukast and were also prescribed theophylline.

Every patient who met GOLD criterion for COPD diagnosis took short acting bronchodilators. Two patients were prescribed ICS (5.9%), 31 took ICS/LABA (91.2%), 5 took LAMA (14.7%), 1 took LTRA (2.9%), and 25 took theophylline (73.5%). All patients with restrictive ventilatory defect were prescribed short acting bronchodilators, 10 took ICS/LABA (90.9%), and 9 took theophylline (81.8%).

## Discussion

Of 168 subjects participated in the study, the majority had history of smoking (72%), involuntarily exposed to tobacco smoke or environmental air pollution. This supports previous studies expressing that the most significant risk factor of COPD was tobacco smoking, together with involuntary exposure to tobacco smoke and environmental air pollution[5-7]. Comorbidities among patients participated in the study were metabolic syndrome and cardiovascular diseases accounting for 43.4%, which is in concordance with previous studies that found the identical comorbidities in COPD patients[8, 9]. Therefore, it is noted that diagnosis and treatment of such comorbidties along with the disease should be done simultaneously.

There were 99 cases (58.9%) had valid spirometry test results according to acceptability criteria and repeatability criteria[4]. Patients with valid ones demonstrated that 34.3% had test results, which met GOLD criterion for COPD diagnosis, i.e., the post-bronchodilator $FEV_1/FVC$ is less than 0.70[5] along

with history of tobacco smoke or exposure to air pollution and onset of COPD symptoms after 40 years of age. This supports previous studies of spirometry test results in patients clinically diagnosed with chronic bronchitis, which found the prevalence of airflow limitation, which were 47.2%[10] and 26%[3]. However, in this study, there were 65.7% of patients who were diagnosed with COPD from clinical manifestations but their spirometry test results did not meet GOLD criterion for COPD diagnosis. This encourages the advantages of taking spirometry because diagnosis of COPD based only on clinical manifestations can be highly erroneous. The study showed that patients who had been diagnosed through observing clinical manifestations as having COPD after performing spirometry were actually found that 9.1% of whom had asthma with fixed obstruction, 2% had asthma, 3% had obstructive ventilatory defect with negative bronchodilator reversibility. These patients accounting for 14.1% were conversely diagnosed as having asthma after performing spirometry. Patients taking spirometry showing the presence of obstructive and restrictive ventilatory defect (22.2%) or restrictive ventilatory defect (11.1%) resulted that there was statistically significant association between the spirometry test results and history of previous pulmonary tuberculosis. This is encouraged by Ehrlich, et al[11]. demonstrated that patients with chronic lung disease caused by previous pulmonary tuberculosis chiefly had spirometry tests with the presence of obstructive and restrictive ventilatory defect. Since there has been high prevalence of the pulmonary tuberculosis in Thailand[12], it is essential to thoroughly diagnose patients with history of pulmonary tuberculosis and risk factors contributing to COPD presenting with chronic cough, chronic progressive dyspnea or chronic productive sputum and distinguish them between developing chronic lung disease resulting from previous pulmonary tuberculosis and developing COPD. The diagnosis cannot be made merely through observation of clinical manifestations, but also depends on spirometry test for insisting diagnosis and providing appropriate treatments. Spirometry test results of 8 patients (8.1%) expressed the presence of obstructive and restrictive ventilatory defect together with history of pulmonary tuberculosis and tobacco smoking or exposure to air pollution. These patients could have developed COPD from smoking or exposure to air pollution and chronic lung disease from previous pulmonary tuberculosis. They might still have benefited from COPD medication. However, 90.9 % of patients showing the presence of restrictive ventilatory defect were prescribed ICS/LABA, which has no evidence of any beneficial effect on them and may also cause unnecessary side effects. In this study, patients who were found having restrictive ventilatory defect, after performing spirometry, were stop prescribing corticosteroid-containing medicine.

Of 69 patients (41.1%) with invalid spirometry test results found that there was statistically significant association between the increased age, mMRC dyspnea scale ≥ 2 or CAT score ≥ 10 and invalid test results. In other hand, there was no association between gender or smoking history and invalid spirometry test results. These findings were in concordance with the previous study demonstrating that increased age affected the quality of spirometry[13]. Meanwhile, the study conducted by Enright, et al.[14] indicated that gender, age, history of smoking and FEV1 (%predicted) values had no effect on quality of spirometry.

## Conclusion

This study showed the importance of spirometry for COPD diagnosis. From this study, there were 58.9% of patients had valid spirometry test results. Those with valid ones demonstrated that 34.3% met GOLD criterion for COPD diagnosis. Factors associated with quality of spirometry test were increased age, mMRC dyspnea scale ≥ 2 or CAT score ≥ 10.

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