Impact of GLI-2012 Spirometric References and Lower Limit of Normal on Prevalence of COPD in Older Urban Thai Persons

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Background: *Previous analysis of survey data from a study in older urban Thai persons reported prevalence of chronic obstructive pulmonary disease (COPD) of 7.11% according to formerly recommended criteria that used fixed ratio (70%) of pre-bronchodilator FEV_1/FVC as the cut-off value. In 2012, the Global Lung Initiative (GLI)-2012 equations for spirometric reference were established and the diagnostic criteria for COPD were changed.*

Objective: *To reanalyze the data collected during the 2002 respiratory health survey to determine prevalence of COPD in older urban Thai persons according to the new GLI-2012 equations.*

Material and Method: *Demographic and clinical data of 3,094 subjects aged ≥60 years from 124 urban communities were re-analyzed. Prevalence of COPD determined by post-bronchodilator FEV_1/FVC and GLI-2012 equations using lower limit of normal by the Lambda-Mu-Sigma method (LMS-LLN) was compared to COPD prevalence findings based on criteria used in previous analysis.*

Results: *Prevalence of COPD in the study population using post-bronchodilator FEV_1/FVC and LMS-LLN was 6.50% (95% CI: 5.63-7.37), compared with 7.82% (95% CI: 6.87-8.77) when fixed ratio (70%) of FEV_1/FVC was used as cut-off. Diagnostic agreement of COPD between LMS-LLN and fixed ratio was high (kappa 0.88, $p<0.0001$). However, 45/242 (18.6%) subjects diagnosed as COPD by fixed ratio criteria were considered as "over-diagnosed" when LMS-LLN was used as the standard cut-off. The same comparison applied to subjects aged ≥80 years revealed an increased rate of over-diagnosis to 7/22 (31.8%) subjects. Higher agreement was observed (kappa 0.95, $p<0.0001$) when comparing between cut-offs for diagnosis of "at least GOLD stage II" COPD.*

Conclusion: *Prevalence of COPD in older urban Thai persons was lower when LMS-LLN was substituted for fixed ratio (70%) of FEV_1/FVC. Agreement in COPD diagnosis between both criteria was high, but a substantial proportion of subjects may be over-diagnosed.*

Keywords: *Aged, COPD, Epidemiology, Prevalence, Spirometry*

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Reference spirometric equations for the Thai adult population (Siriraj equations)[1] were established in 2000 and have since been widely used for interpretation of spirometry in Thailand. In 2002, a respiratory health survey conducted among the elderly population in Bangkok metropolis[2] using Siriraj equations as spirometric references yielded chronic obstructive pulmonary disease (COPD) prevalence of 7.11%. Methods and criteria used in the 2002 survey differ from the methods and criteria later recommended in subsequent versions of Global Initiative for Obstructive Lung Disease (GOLD) guidelines[3]. For example, pre-bronchodilator FEV_1/FVC with negative reversibility test was used for diagnosing COPD in the 2002 survey. GOLD now recommends post-bronchodilator FEV_1/FVC for diagnosing COPD. The 2002 survey collected both pre- and post-bronchodilator spirometric values.

Analysis of the 2002 survey data used a fixed ratio value of 70% of FEV_1/FVC as the cut-off for defining airflow obstruction, as recommended by GOLD guideline[3]. Debate within the medical community continues regarding the criteria used for diagnosis of airflow obstruction in COPD. Some respiratory physicians and researchers[4,5] have proposed a "fifth centile" as the lower limit of normal instead of the fixed ratio. In 2012, the Global Lung Function Initiative (GLI) established universal equations (GLI-2012 equations) that can be used

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around the world as reference spirometric values[6,7]. These equations, which were derived by the Lambda-Mu-Sigma method, can be used globally to calculate predicted spirometric values and the lower limit of normal (LMS-LLN). The authors were compelled to investigate the effect of using GLI-2012 references and LMS-LLN in place of using fixed ratio of FEV_1/FVC in determining prevalence of COPD in older urban Thai persons.

The authors, therefore, set forth to reanalyze the data collected during the 2002 survey to determine prevalence of COPD in older urban Thai persons according to the new GLI-2012 spirometric equations and lower limit of normal.

Material and Method

Data from the cross-sectional survey conducted in 2002 was retrieved for reanalysis. The 2002 survey was conducted among older urban Thai persons aged 60 years or more who resided in 124 communities located within a 10 km radius of Siriraj Hospital (Bangkok, Thailand). In that study, data relating to demographics, respiratory health, smoking status, spirometry, and chest radiography was collected. Pre- and post-bronchodilator (400 micrograms of salbutamol) spirometry was performed in each participant using similar model of electronic pneumotachometer (Pony Graphics 3.0) that met American Thoracic Society standard[8].

Criteria used to define airflow obstruction in the previous report[2] was ratio of FEV_1/FVC less than 70%, FEV_1 reversibility of less than 15%, and absence of parenchymal lesions or cardiomegaly in chest radiographs. Prevalence of COPD in this population according to these criteria was reported to be 7.11%.

Spirometry data from 3,094 subjects were used in this study, including FVC, FEV_1, FEV_1/FVC, and MEF. The 2002 data were then re-analyzed according to various diagnostic criteria and different reference spirometric equations. Previous predicted values (Siriraj equations) were calculated from the equations reported by Dejsomritrutai et al[1]. GLI-2012 predicted values and the lower limit of normal (LMS-LLN) for each case were then calculated according to the GLI-2012 equations reported by Quanjer et al[6,7]. The protocol for this study was approved by Siriraj Institutional Review Board (SIRB).

Definitions

Various criteria were used for diagnosis of COPD. Criteria included different cut-offs for FEV_1/FVC, including fixed value (70%) of FEV_1/FVC versus LMS-LLN by GLI-2012 equations and pre-bronchodilator versus post-bronchodilator spirometric values. Prevalence of COPD of at least GOLD stage II (FEV_1 <80% predicted by GLI-2012 equations) was also determined.

Statistical methods

Descriptive statistics were used to describe prevalence of COPD in the study population. Kappa statistic was used to determine agreement between diagnoses made using different criteria. SPSS version 18.0 (SPSS: Chicago, IL) software was used for statistical analysis.

Results

Demographic and characteristic data of subjects are shown in Table 1. Prevalence of COPD according to various diagnostic criteria is shown in Table 2. Previously reported prevalence of COPD is represented as COPD-A. For this category, 70% fixed ratio of pre-bronchodilator FEV_1/FVC was the cut-off and subjects with FEV_1 reversible ≥15% were excluded. This yielded COPD prevalence of 7.11% (95% CI: 6.20-8.02). When post-bronchodilator values were used regardless of reversibility test (COPD-B), prevalence increased to 7.82% (95% CI: 6.87-8.77). However, if the LMS-LLN calculated from GLI-2012 equations was used as cut-off for FEV_1/FVC, prevalence (COPD-C) decreased to 6.50% (95% CI: 5.63-7.37).

Diagnostic agreement between fixed ratio and LMS-LLN as cut-offs is shown in Table 3. Although kappa statistic revealed good overall agreement (kappa 0.88, p<0.0001), there were 49 subjects for whom COPD diagnosis was different between fixed ratio and LMS-LLN. Most cases (45 subjects) were diagnosed as COPD by fixed ratio criteria, but not by LMS-LLN. Accordingly and relative to the population size in this study, if LMS-LLN were used as the standard cut-off for diagnosis, 18.6% (45/242) of COPD cases would classify as being over-diagnosed.

It has been reported that asymptomatic GOLD stage I COPD had no significant differences in FEV_1 decline, respiratory care utilization, or quality of life, as compared with healthy subjects[9]. Some researchers thus consider that GOLD stage I COPD does not represent disease[10]. The study of subjects with COPD of at least GOLD stage II may provide more clinical meaning. Prevalence of COPD with at least GOLD stage II is presented in Table 4. GLI-2012 equations

Table 1. Demographic and clinical data of 3,094 Thai urban older persons

	Male, mean (SD)	Female, mean (SD)	All, mean (SD)
n	1,124	1,970	3,094
Age (year)	68.1 (6.3)	67.7 (6.4)	67.9 (6.4)
Height (cm)	162.7 (6.5)	151.0 (6.0)	155.3 (8.3)
Weight (kg)	60.7 (11.0)	56.0 (11.0)	57.7 (11.2)
BMI (kg/m^2)	22.9 (3.8)	24.5 (4.4)	23.9 (4.3)
FEV_1, pre-BD (L)	2.01 (0.53)	1.54 (0.35)	1.71 (0.48)
FVC, pre-BD (L)	2.61 (0.56)	1.85 (0.38)	2.12 (0.59)
FEV_1/FVC, pre-BD (%)	76.6 (10.4)	83.0 (7.0)	80.7 (8.9)
FEV_1, post-BD (L)	2.07 (0.52)	1.58 (0.34)	1.76 (0.47)
FVC, post-BD (L)	2.68 (0.55)	1.89 (0.38)	2.17 (0.59)
FEV_1/FVC, post-BD (%)	77.0 (10.5)	83.8 (7.1)	81.3 (9.1)

BMI = body mass index; FEV = forced expiratory volume; FVC = forced vital capacity; pre-BD = pre-bronchodilator; post-BD = post-bronchodilator

Table 2. Prevalence of COPD according to various diagnostic criteria

	Diagnostic criteria	n (total = 3,094)	Prevalence, % (95% CI)
COPD-A	Pre-bronchodilator Fixed ratio of FEV_1/FVC <70% Exclude reversible ≥15%	220	7.11 (6.20-8.02)
COPD-B	Post-bronchodilator Fixed ratio of FEV_1/FVC <70%	242	7.82 (6.87-8.77)
COPD-C	Post-bronchodilator LMS-LLN of FEV_1/FVC	201	6.50 (5.63-7.37)

COPD = chronic obstructive pulmonary disorder; FEV = forced expiratory volume; FVC = forced vital capacity; LMS-LLN = lower limit of normal by Lambda-Mu-Sigma method in Global Lung Initiative (GLI)-2012 equations

Table 3. Diagnostic agreement of COPD between fixed FEV_1/FVC criteria and LMS-LLN

Fixed ratio	LMS-LLN			Kappa
	Non-COPD	COPD	Total	
Age ≥60 years				
Non-COPD	2,848	4	2,852	0.88;
COPD	45	197	242	p<0.0001
Total	2,893	201	3,094	
Age ≥80 years				
Non-COPD	165	0	165	0.79;
COPD	7	15	22	p<0.0001
Total	172	15	187	

COPD = chronic obstructive pulmonary disorder; LMS-LLN = lower limit of normal by Lambda-Mu-Sigma method in GLI-2012 equations

were used for calculation of predicted FEV_1. Agreement in diagnosis of COPD with at least GOLD stage II between fixed ratio and LMS-LLN cut-offs is shown in Table 5. Kappa statistic revealed better agreement (kappa 0.95, p<0.0001), with a smaller number of subjects having diagnostic discrepancy. If LMS-LLN is used as the gold standard cut-off value, a smaller proportion (8.94%, 16/179) of COPD cases would be regarded as being over-diagnosed.

Discussion

Debate continues among respiratory physicians and researchers regarding the cut-off value of FEV_1/FVC for the lower limit of normal[11-13]. An arbitrary fixed ratio of 70% has been used, although there is evidence that FEV_1/FVC and its lower limit of normal are varied by age as similar to other spirometric parameters, such as FEV_1, FVC, and MEF. One notable reason why the 70% value was widely adopted and used relates to the complexity of using the fifth centile value. Modern spirometers, however, now have the necessary functions to perform these calculations. GLI-2012 introduced universally applicable equations for reference spirometric values, including the lower

Table 4. Prevalence of "at least GOLD stage II" COPD according to post-bronchodilator FEV_1/FVC, comparing between fixed ratio and LMS-LLN of GLI-2012 equations as cut-offs

FEV_1/FVC cut-off	Equation for FEV_1 predicted	n (total = 3,094)	Prevalence % (95% CI)
Fixed 70%	GLI-2012	179	5.79 (4.96-6.61)
LMS-LLN	GLI-2012	164	5.30 (4.51-6.09)

GOLD = Global Initiative for Chronic Obstructive Lung Disease; FEV = forced expiratory volume; FVC = forced vital capacity; LMS-LLN = lower limit of normal by Lambda-Mu-Sigma method in GLI-2012 equations

Table 5. COPD of at least GOLD stage II (GOLD II+): diagnostic agreement between fixed ratio and LMS-LLN of GLI-2012 equations as cut-offs

	LMS-LLN		
	Non-GOLD II	GOLD II+	Total
Non-GOLD II	2,914	1	2,915
GOLD II+	16	163	179
Total	2,930	164	3,094

GOLD = Global Initiative for Chronic Obstructive Lung Disease
Kappa 0.95; $p<0.0001$

limit of normal[6]. This provides an opportunity for transition from use of a fixed ratio to use of a lower limit of normal for FEV_1/FVC. Moreover, significant studies have shown that subjects, especially older persons, were over-diagnosed as COPD when fixed ratio was used instead of LMS-LLN as the lower limit of normal[12,14]. Most studies were conducted in groups of clinical subjects. The present study, however, presents epidemiological evidence of the impact of using different cut-offs in a more generalized population of older people.

Although there was good agreement (kappa 0.88, $p<0.0001$) in COPD diagnosis between both cut-offs (Table 3), a substantial proportion of subjects (45/242, 18.6%) would be considered to be over-diagnosed as COPD if the LMS-LLN value is used. Moreover, in subjects aged older than 80 years (n = 187), over-diagnosed cases of COPD were seven in 22 (31.8%). Disagreement in very old population (age older than 80 years) was more obvious (kappa coefficient less than 0.4) in the study recently reported by Turkeshi et al[15]. The level of acceptable misdiagnosis is subjective and is worthy of added consideration and study. In addition to consideration of clinical issues, that discussion should also consider relevant psychosocial and economic factors. A report from a study in older Caucasian persons revealed substantial discrepancy in respiratory impairment classification between the LMS-LLN and GOLD approaches[14,15]. Additionally, Fragoso et al recently published an epidemiological study in an aging population in which 13.4% of GLI-2012-defined normal spirometry was regarded as COPD by GOLD criteria[16].

Recent studies have provided useful information for an alternative approach. Bridevaux et al reported that GOLD stage I COPD subjects (asymptomatic) had no significant differences in FEV_1 decline, respiratory care utilization, or quality of life, as compared with healthy subjects[9]. Analysis in subjects with FEV_1 <80% predicted (at least GOLD stage II) may provide more meaningful clinical results. We, therefore, compared the prevalence of at least GOLD stage II COPD between both cut-offs for FEV_1/FVC. More diagnostic agreement (kappa 0.95, $p<0.0001$) and less over-diagnosed cases (16/179, 8.94%) was the result (Table 5). Prevalence in both methods was found to be comparable, as shown in Table 4.

The previously reported prevalence of COPD in our population of older urban Thai persons[2] (COPD-A) was 7.11% (Table 2). Prevalence increased to 7.82% (COPD-B) when post-bronchodilator FEV_1/FVC was used instead of pre-bronchodilator values, combined with exclusion of subjects with positive reversibility test. This may be due to a lack of awareness in a group of patients that had characteristics that overlapped between asthma and COPD in the previous study[2]. This group was therefore diagnosed as asthma and was excluded from COPD group. This phenotype of COPD is referred to as asthma-COPD overlap syndrome (ACOS).

This study presents information regarding the impact of GLI-2012 equations, especially LMS-LLN, on diagnosis of COPD in the general population of older urban Thai persons. However, this study had some inherent limitations. One limitation involves the lack of awareness of the existence of a later defined phenotype of ACOS, resulting in the incomplete collection of some important data. Another limitation involves that the discordant group cannot be traced for further study.

In conclusion, lower prevalence of COPD in older urban Thai persons was observed when GLI-2012 equations were used instead of fixed ratio (70%) of FEV_1/FVC. Agreement in COPD diagnosis between both criteria was high, but a substantial proportion of subjects may be over-diagnosed as COPD.

What is already known on this topic?

Debate continues within the medical community regarding the spirometric criteria used to define airway obstruction. Over the past decade, recommendations from global organizations have changed. In place of pre-bronchodilator value of FEV_1/FVC, post-bronchodilator value of FEV_1/FVC is now recommended. Although the GLI-2012 equations were recently established as a global reference for spirometry, controversy remains regarding the cut-off value between fixed ratio of 70% and lower limit of normal (the fifth centile) of FEV_1/FVC.

What this study adds?

This study presents data relating to the epidemiological impact of the newly established use of post-bronchodilator spirometric value and the new global spirometric reference values, including the lower limit of normal, on COPD prevalence in a large community-based population of older urban Thai persons.

Potential conflicts of interest

None.

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ผลกระทบของการปรับใช้สมการค่ามาตรฐานสมรรถภาพปอดสากลและเกณฑ์ขั้นต่ำของ FEV_1/FVC ต่อค่าความชุกของโรคปอดอุดกั้นเรื้อรังในประชากรผู้สูงอายุที่อาศัยในเขตเมือง

วันชัย เดชสมฤทธิ์ฤทัย, เบญจมาศ ช่วยชู

ภูมิหลัง: *ผลการสำรวจในประชากรไทยผู้สูงอายุที่อาศัยในเขตเมืองก่อนหน้านี้พบว่ามีค่าความชุกของโรคปอดอุดกั้นเรื้อรังร้อยละ 7.11 ทั้งนี้โดยใช้เกณฑ์การวินิจฉัยโรคที่ได้รับคำแนะนำในขณะนั้น เช่น การใช้ค่าสัดส่วนคงที่ (ร้อยละ 70) ของ FEV_1/FVC ก่อนได้รับยาขยายหลอดลมเป็นเกณฑ์ ไม่นานมานี้ได้มีรายงานสมการคำนวณค่ามาตรฐานสมรรถภาพปอดที่เป็นสากล (Global Lung Initiative (GLI)-2012) รวมทั้งได้มีการปรับปรุงเกณฑ์การวินิจฉัยโรคปอดอุดกั้นเรื้อรังขึ้นใหม่*

วัตถุประสงค์: *ศึกษาผลกระทบของการปรับใช้สมการค่ามาตรฐานสมรรถภาพปอดสากลต่อค่าความชุกของโรคปอดอุดกั้นเรื้อรังในประชากรผู้สูงอายุในเขตเมือง*

วัสดุและวิธีการ: *คณะผู้นิพนธ์ได้นำข้อมูลที่ได้จากการสำรวจของการศึกษาก่อนหน้า ซึ่งครอบคลุมประชากรไทยที่อาศัยในชุมชนเขตเมือง 124 ชุมชน อายุตั้งแต่ 60 ปีขึ้นไป จำนวน 3,094 ราย นำมาวิคราะห์ซ้ำเพื่อหาค่าความชุกของโรคปอดอุดกั้นเรื้อรังโดยใช้เกณฑ์ปัจจุบัน ได้แก่ ค่า FEV_1/FVC หลังได้รับยาขยายหลอดลม และใช้ค่าเกณฑ์ขั้นต่ำ (lower limit of normal) ของ FEV_1/FVC ที่ได้จากวิธี Lambda Mu Sigma (LMS-LLN) โดยสมการของ GLI-2012 เปรียบเทียบกับค่าความชุกที่ได้จากการศึกษาก่อนหน้า*

ผลการศึกษา: *ค่าความชุกของโรคปอดอุดกั้นเรื้อรังโดยใช้ ค่า FEV_1/FVC หลังได้รับยาขยายหลอดลมและใช้ค่า LMS-LLN เป็นเกณฑ์การวินิจฉัย คือ ร้อยละ 6.50 (95% CI: 5.63-7.37) เปรียบเทียบกับ ร้อยละ 7.82% (95% CI: 6.87-8.77) เมื่อใช้สัดส่วนคงที่ (ร้อยละ 70) เป็นเกณฑ์ ผลการวิเคราะห์ความสอดคล้องของการวินิจฉัย (diagnostic agreement) พบว่ามีค่าสูง (kappa 0.88, $p<0.0001$) อย่างไรก็ตามหากใช้ LMS-LLN เป็นเกณฑ์มาตรฐานในการวินิจฉัยโรค พบว่า ประชากรที่ได้รับการวินิจฉัยเป็นโรคปอดอุดกั้นเรื้อรังจากเกณฑ์สัดส่วนคงที่ จะได้รับการวินิจฉัยคลาดเคลื่อนเกิน (over-diagnosed) เป็นจำนวน 45 ใน 242 ราย (ร้อยละ 18.6) และพบสูงขึ้นเป็น 7 ใน 22 ราย (ร้อยละ 31.8) ในกลุ่มที่มีอายุตั้งแต่ 80 ปีขึ้นไป การวิเคราะห์เพิ่มเติมพบว่า ความสอดคล้องของการวินิจฉัยโรคระหว่างเกณฑ์ LMS-LLN และเกณฑ์สัดส่วนคงที่จะเพิ่มขึ้นหากใช้ในการวินิจฉัยโรคปอดอุดกั้นเรื้อรังตั้งแต่ระดับความรุนแรงที่ 2 (GOLD stage II) ขึ้นไป (kappa 0.95, $p<0.0001$)*

สรุป: *ความชุกของโรคปอดอุดกั้นเรื้อรังในประชากรไทยผู้สูงอายุที่อาศัยในเขตเมืองมีค่าลดลงเมื่อใช้เกณฑ์ขั้นต่ำของ FEV_1/FVC จากวิธี LMS-LLN แทนการใช้สัดส่วนคงที่ (ร้อยละ 70) ความสอดคล้องของการวินิจฉัยโรคอยู่ในเกณฑ์สูง อย่างไรก็ตาม การใช้เกณฑ์สัดส่วนคงที่อาจทำให้เกิดความคลาดเคลื่อนในการวินิจฉัยโรคในประชากรส่วนหนึ่ง*