Quality Assurance of Spirometry for COPD Clinic Accreditation in Thailand

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Objective: *To evaluate quality of spirometry for COPD clinic accreditation.*
Material and Method: *A minimum of 25 spirograms from each of 38 hospitals were evaluated using the American Thoracic Society (ATS)/European Respiratory Society (ERS) acceptability criteria. Technicians were separated into two groups based on their respective level in spirometry training, previously trained-certified, and naïve (not formally trained-certified) groups. Unpaired t-test and Chi-square were used to compare differences between the two groups. Statistical significance was set at p<0.05.*
Results: *Thirty-eight technicians from 38 clinics submitted a total of 1,556 spirograms for accreditation evaluation. Of those, 1,066 (68.5%) spirograms met all ATS/ERS acceptability criteria. Only 47.4% of the clinics received an A grade. All clinics that received an A grade were staffed by trained-certified technicians. Significantly, more spirograms failed to meet the criteria from clinics with naïve technicians than clinics with trained-certified technicians (18.2% vs. 80.8%, p-value <0.001). Criteria where the trained-certified group significantly achieved than naive group were satisfactory exhalation (93.4% vs. 20.9%, p-value <0.001), no early termination (98.5% vs. 58.6%, p-value <0.001), maximal effort throughout (96.2% vs. 89.1%, p-value <0.001), and good start (91.6% vs. 79.9%, p-value <0.001).*
Conclusion: *Spirometry performed by the Thoracic Society of Thailand trained-certified technician was distinguishably higher quality than by a naïve technician. Our results are a reminder of the importance of quality assurance for spirometry in clinical practice.*

Keywords: *Spirometry, Chronic obstructive pulmonary disease, Train, Technician*

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Spirometry is a basic tool to evaluate function of the respiratory system, confirm normality, detect, and classify potential respiratory patterns, as well as an indication of degree of severity of the disease[1]. However, the recommended criteria for acceptability and reproducibility of spirometry are difficult to fulfill. This approach has limitations, because the routine use of spirometry in primary care is infrequent[2] and technical quality is poor[3,4]. This fact is largely explained by the difficulty encountered by primary care staff in performing technically acceptable spirometries[3]. If spirometry is to be promoted as a screening tool in primary care practice, careful attention is needed to ensure that quality standards are met. However, the results achieved, in terms of standard criteria, are not always satisfactory[3]. The disparity in standards was persuasively addressed in the spirometry in the Lung Health Study: I and II particularly with regard to the importance of ongoing maintenance of standards[5,6]. Hence, effective training and quality assurance are inextricably linked for successful spirometry[7]. Quality assurance is crucial to prevent misleading result and misdiagnosis. The present study aimed to assess the quality of spirograms sent from 38 hospitals, to accredit chronic obstructive pulmonary disease (COPD) clinics using the American Thoracic Society/European Respiratory Society (AST/ERS) acceptability criteria, to identify the most common errors in not meeting AST/ERS criteria, and the impact of the Thoracic Society of Thailand (TST) training-certification program.

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Material and Method

Study design

Thirty-eight spirometry technicians, from COPD clinics of 12 provincial and 26 community hospitals in Thailand were asked to send self-selected spirograms performed within six months in their

routine clinical practices to be used for accreditation of COPD clinics in Thailand. A technician from each hospital was advised to select and send at least 25 spirograms. Complete spirograms were composed of a paired volume-time curve and flow-volume loop test using a standard spirometer at each hospital. All spirograms were sent via e-mail, and evaluated blindly (hospital affiliation and technician name masked) by one pulmonologist and two qualified technicians from the pulmonary function laboratory of Chiang Mai University Hospital, Chiang Mai, Thailand. Any spirogram that all three did not independently agree on was resolved as a group. Technicians who submitted spirograms were separated into two groups based on their previous experiences in spirometry training. Technicians who had received certification after attending a 5-day spirometry training course organized by TST within the past two years were grouped as TST trained-certified group. The uncertified technicians were grouped as naïve group. The TST-training program, consists of four hours of lectures, and 24 hours of workshops covering various aspects of the disease to be investigated, the rationale and practice of spirometry with the American ATS/ERS standardized procedures[1]. The program included individual and group sessions on the calibration, use, and maintenance of a spirometer. At the end of the training course practitioners had to complete a written and practical examination to verify their understanding of the material, and all were certified by TST after passing both examinations. Ethics approval was granted by the Ethics Committee of the Faculty of Medicine, Chiang Mai University [Institutional Review Board (IRB) approval number: MED-2558-02906, date of approval: 26 March 2015].

Quality assessment

Each hospital was assigned a quality grading from A to F according to the International Grade Equivalencies[8] based on the percentages of spirograms that met ATS/ERS acceptability criteria[1] (Table 1). For accreditation, the COPD clinic needed to achieve an overall A grade. A list of 8 acceptability criteria were assessed as quality indicators of spirograms, including: no cough during the first second of exhalation or any other cough, no glottis closure, no early termination or cut-off, maximal effort throughout, no leak, mouthpiece not obstructed, good start (back-extrapolated volume as defined by an extrapolated volume >5% of forced vital capacity (FVC) or 0.150 L, whichever is greater), and satisfactory exhalation (satisfactory duration of exhalation ≥6 seconds or a plateau in the volume-time curve)[1].

Table 1. Spirometry quality characterized by grading[8]

Grading classification	Percent of acceptable spirograms
A	≥80
B	70 to <80
C	60 to <70
D	50 to <60
F	<50

Sample size calculation

Sample size calculation was based on the difference of practitioners performing "acceptable" spirometry between the trained group (67%) and the usual group (16%) in the previous study[3]. We needed to study 30 trained practitioners and six naïve practitioners to be able to reject the null hypothesis that the proportions of the trained practitioners and naïve practitioners were equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05 and the sampling ratio of the trained practitioners and naïve practitioners are 5:1.

Statistical analysis

Data were normally distributed and were presented as mean ± SD or n (%). The difference in the highest number of spirograms that met acceptable criteria was compared between TST trained-certified and naïve groups of technicians. Categorical variables were analyzed using the Chi-square test. Continuous variables were compared using independent t-test. A *p*-value <0.05 was considered as statistically significant. All analyses were carried out using SPSS for Windows, version 16 (Chicago, SPSS Inc.).

Results

One thousand five hundred fifty six spirograms were sent from 38 COPD clinics of 12 provincial and 26 community hospitals in Thailand. The mean age of tested subjects was 57.9±15.3 years old, and 1,074 (69.0%) were male. The technicians were mostly nurses, 26 (68.4%), while 12 (31.6%) were physical therapists. Thirty-two (84.2%) technicians had been trained and certified by TST (Table 2). There was no discordant agreement among the auditors on acceptability criteria for any spirograms. The quality grading for all hospitals based on groups of technicians and based on levels of hospital care were demonstrated

Table 2. Characteristics of spirogram and spirometry technicians in study

Variables	Mean ± SD or n (%)
Number of spirograms	1,556
Tested subject	
Age of tested subject (years)	57.9±15.3
Male gender	1,074 (69.0)
Level of hospital	
Provincial hospital	12 (31.6)
Community hospital	26 (68.4)
Technician	
Nurse	26 (68.4)
Physical therapist	12 (31.6)
Previously-certified training	32 (84.2)
Naïve	6 (15.8)

Data are presented in number (%), mean ± SD

Table 3. Spirometry quality grading for all hospitals based on technician group

Grading	Technician groups, n (%)			*p*-value
	TST trained-certified (n = 32)	Naïve (n = 6)	Total (n = 38)	
A	18 (56.2)	0 (0.0)	18 (47.4)	<0.001
B	6 (18.8)	0 (0.0)	6 (15.8)	
C	6 (18.8)	0 (0.0)	6 (15.8)	
D	1 (3.1)	1 (16.7)	2 (5.2)	
F	1 (3.1)	5 (83.3)	6 (15.8)	

TST = Thoracic Society of Thailand
Data are presented in number (%); *p*-value, indicates statistically significant difference between TST trained-certified and naïve groups

Table 4. Spirometry quality grading for all hospitals by level of hospital

Grading classification	Levels of hospital, n (%)			*p*-value
	Provincial hospitals (n = 12)	Community hospitals (n = 26)	Total (n = 38)	
A	8 (66.7)	10 (38.5)	18 (47.4)	0.082
B	2 (16.7)	4 (15.4)	6 (15.8)	
C	1 (8.3)	5 (19.2)	6 (15.8)	
D	0 (0.0)	2 (7.7)	2 (5.2)	
F	1 (8.3)	5 (19.2)	6 (15.8)	

Data are presented in number (%)

in Table 3 and Table 4, respectively. Less than 50% of hospitals evaluated received the highest A grade, all of which had a TST trained-certified technician performing the test (Table 3). Although the provincial hospitals tended to pass the accreditation criteria more than community hospitals, there was no statistical significance (Table 4).

Acceptability criteria of spirograms

Of all spirograms sent by the COPD clinics for accreditation review only a moderate percentage passed all acceptability criteria (1,066, 68.5%). The comparison of 8 acceptability criteria for spirogram quality between the two groups of technicians was demonstrated (Table 5). The spirograms from the TST trained-certified group met acceptability criteria significantly more often (80.2%) than those of the naïve group (18.1%). The four criteria where the trained-certified group significantly achieved than naive group were satisfactory exhalation (93.4% vs. 20.9%, *p*-value <0.001), no early termination (98.5% vs. 58.6%, *p*-value <0.001), maximal effort throughout (96.2% vs. 89.1%, *p*-value <0.001), and good start (91.6% vs. 79.9%, *p*-value <0.001).

Discussion

This was the first study to formally address the quality of spirograms for COPD clinic accreditation in Thailand using well defined, standard, and objective criteria of ATS/ERS[1]. We believed that meeting acceptability criteria was a good measure for assessing the effect of TST provided training and certification programs. The assessment of acceptable spirograms did translate into acceptable spirometry when routinely performed in clinical practice. Our results revealed unsatisfactory percentages of accredited COPD clinics in hospitals. All accredited clinics were staffed with TST trained-certified technicians. The significance of training was demonstrated clearly as the high percentage of spirograms that complied with all 8 ATS/ERS acceptability criteria for COPD clinics staffed by TST trained-certified technicians as compared to naïve technicians. Our results were similar to a previous study that determined trained nurses performing spirometry met ATS/ERS standards for acceptability 76% of the time[9]. In another study showed the group with training could achieve a higher proportion than the group without training (67% and 16%)[3]. A number of primary care studies demonstrated that spirometry did not always meet good quality standards[10-12], however, with adequate and appropriate training, primary care practitioners are able to obtain high quality tests[13].

Although the training effect in the present study was obvious, less than half of the hospitals

Table 5. Comparison of acceptability criteria compliance between TST trained-certified vs. naïve groups

Items of acceptability	Spirogram by groups of technicians						*p*-value
	Previously-certified training (n = 1,252)		Naïve (n = 304)		Total (n = 1,556)		
	Yes	No	Yes	No	Yes	No	
Not cough during the 1st second of exhalation or no any other cough	1,236 (98.7)	16 (1.3)	302 (99.3)	2 (0.7)	1,538 (98.5)	18 (1.2)	0.364
No glottis closure	1,246 (99.5)	6 (0.5)	304 (100.0)	0 (0.0)	1,550 (99.6)	6 (0.4)	0.227
No early termination or cut-off	1,233 (98.5)	19 (1.5)	178 (58.6)	126 (41.4)	1,411 (90.7)	145 (9.3)	<0.001
No effort that is not maximal throughout	1,205 (96.2)	47 (3.8)	271 (89.1)	33 (10.9)	1,476 (94.9)	80 (5.1)	<0.001
No leak	1,247 (99.6)	5 (0.4)	300 (98.7)	4 (1.3)	1,547 (99.4)	9 (0.6)	0.059
Not obstructed mouthpiece	1,251 (99.9)	1 (0.1)	304 (100.0)	0 (0.0)	1,555 (99.9)	1 (0.1)	0.622
Good starts	1,147 (91.6)	105 (8.4)	243 (79.9)	61 (20.1)	1,390 (89.3)	166 (10.7)	<0.001
Show satisfactory exhalation	1,169 (93.4)	83 (6.6)	91 (29.9)	213 (70.1)	1,260 (81.0)	296 (19.0)	<0.001
Met all items of acceptability	1,011 (80.8)	241 (19.2)	55 (18.1)	249 (81.9)	1,066 (68.5)	490 (31.5)	<0.001

TST = Thoracic Society of Thailand

Data are presented in number (%); *p*-value, indicates a statistically significant difference between TST trained-certified and naïve groups

achieved accreditation for qualified spirograms. Provincial hospitals tended to pass the accreditation more than community hospitals. The possible explainable reason was that provincial hospitals might have more cases for practicing spirometry. The hospitals that failed the accreditation might be under practicing spirometry in clinical practice as demonstrated by a Canadian study[14]. The provision of spirometry, where quality issues can be addressed and maintained, may only be achieved by limiting spirometry to a smaller number of community clinics or pulmonologists or by increasing access to pulmonary function laboratories where quality-control measures are already in place[15].

The strengths of the present study were firstly focusing on training qualification of spirometry technicians and levels of hospitals' COPD clinics by blind evaluation. Secondly, all objective items of acceptability criteria were evaluated by the agreement of three pulmonary function specialists or a group consensus of disparity. Thirdly, the audited spirogram sent via e-mail was an inexpensive and highly reliable method of communication. However, the study had some limitations to be mentioned: firstly, our analysis based on data via e-mail might not be highly reliably as comparing with face to face assessment. Secondly, the interval from training to accreditation and the average numbers of spirometry performed were not available for analysis. Thirdly, there was no third party randomly selected spirograms sent for accreditation. Therefore, a selection bias of the spirograms from each technician might confound the study results. Fourthly, the present study did not include reproducibility criteria because the technicians selected only the best spirogram of a test for assessment. Further study for standards of accreditation for spirometry should accredit randomly selected spirograms and assess both acceptability and reproducibility criteria.

Conclusion

Less than half of COPD clinics were accredited. All accredited clinics were staffed by TST trained-certified technicians performed spirometry. Only a moderate number of spirograms met all acceptability criteria. Spirometry performed by a TST trained-certified technician was of distinguishably higher quality than by a naïve technician. Our results are a reminder of the importance of quality assurance for spirometry in clinical practice.

What is already known on this topic?

In the previous study showed the group with training technicians could achieve a higher proportion than the group without training[3]. However, there has been no evaluating quality of spirometry for COPD clinic accreditation in Thailand.

What this study adds?

This is the first study to formally address the quality of spirograms for COPD clinic accreditation in Thailand, using well defined, standard, and objective criteria of ATS/ERS[1].

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Potential conflicts of interest

None.

References

1. Miller MR, Hankinson J, Brusasco V, Burgos F, Casaburi R, Coates A, et al. Standardisation of spirometry. Eur Respir J 2005; 26: 319-38.
2. Caramori G, Bettoncelli G, Tosatto R, Arpinelli F, Visona G, Invernizzi G, et al. Underuse of spirometry by general practitioners for the diagnosis of COPD in Italy. Monaldi Arch Chest Dis 2005; 63: 6-12.
3. Eaton T, Withy S, Garrett JE, Mercer J, Whitlock RM, Rea HH. Spirometry in primary care practice: the importance of quality assurance and the impact of spirometry workshops. Chest 1999; 116: 416-23.
4. White P, Wong W, Fleming T, Gray B. Primary care spirometry: test quality and the feasibility and usefulness of specialist reporting. Br J Gen Pract 2007; 57: 701-5.
5. Enright PL, Johnson LR, Connett JE, Voelker H, Buist AS. Spirometry in the Lung Health Study. 1. Methods and quality control. Am Rev Respir Dis 1991; 143: 1215-23.
6. Enright PL, Connett JE, Kanner RE, Johnson LR, Lee WW. Spirometry in the Lung Health Study: II. Determinants of short-term intraindividual variability. Am J Respir Crit Care Med 1995; 151: 406-11.
7. American Thoracic Society. Standardization of spirometry, 1994 update. Am J Respir Crit Care Med 1995; 152: 1107-36.
8. The Graduate School & International Admissions. International grade equivalencies [Internet]. 2014 [cited 2015 Nov 3]. Available from: http://www.unco.edu/CIE/studyabroad/Documents/Grade%20Equivalencies.pdf
9. Walters JA, Hansen EC, Johns DP, Blizzard EL, Walters EH, Wood-Baker R. A mixed methods study to compare models of spirometry delivery in primary care for patients at risk of COPD. Thorax 2008; 63: 408-14.
10. Mulder HH, van der Molen T, Postma DS. Measuring FEV1 in general practice. Eur Resp J 1996; 9 (Suppl 22): S121.
11. Woolhouse I, O'Hickey SP. Accuracy of spirometry measured in general practice compared to a hospital pulmonary function laboratory. Eur Resp J 1999; (Suppl 14): S273.
12. den Otter JJ, Knitel M, Akkermans RP, van Schayck CP, Folgering HT, van Weel C. Spirometry in general practice: the performance of practice assistants scored by lung function technicians. Br J Gen Pract 1997; 47: 41-2.
13. Schermer TR, Jacobs JE, Chavannes NH, Hartman J, Folgering HT, Bottema BJ, et al. Validity of spirometric testing in a general practice population of patients with chronic obstructive pulmonary disease (COPD). Thorax 2003; 58: 861-6.
14. Kesten S, Chapman KR. Physician perceptions and management of COPD. Chest 1993; 104: 254-8.
15. Gardner RM, Clausen JL, Crapo RO, Epler GR, Hankinson JL, Johnson JL, Jr., et al. Quality assurance in pulmonary function laboratories. Am Rev Respir Dis 1986; 134: 625-7.

การตรวจประเมินคุณภาพผลการตรวจสมรรถภาพปอดสำหรับคลินิกปอดอุดกั้นเรื้อรังในประเทศไทย

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วัตถุประสงค์: *เพื่อประเมินคุณภาพผลการตรวจสมรรถภาพปอดของเจ้าหน้าที่คลินิกโรคปอดอุดกั้นเรื้อรังในประเทศไทย*

วัสดุและวิธีการ: *เจ้าหน้าที่ซึ่งมีหน้าที่ในการตรวจสมรรถภาพปอดจาก 38 โรงพยาบาล ได้ส่งผลการตรวจสมรรถภาพปอดมาอย่างน้อยคนละ 25 ผล เพื่อรับการประเมินคุณภาพโดยใช้เกณฑ์ตามมาตรฐานของสมาคมโรคทรวงอกแห่งอเมริกาและสมาคมโรคระบบการหายใจแห่งยุโรป เจ้าหน้าที่ผู้ตรวจสมรรถภาพปอดแต่ละคลินิกโรคปอดอุดกั้นเรื้อรังจากแต่ละโรงพยาบาลนั้นจะถูกแบ่งออกเป็นสองกลุ่มคือ กลุ่มที่ได้และไม่ได้รับการฝึกอบรมหรือรับรองจากสมาคมอุรเวชช์แห่งประเทศไทย การเปรียบเทียบผลการตรวจประเมินระหว่างกลุ่มใช้สถิติ Unpaired t-test และ Chi-square ซึ่งกำหนดค่าความแตกต่างอย่างมีนัยสำคัญทางสถิติไว้ที่ p-value <0.05*

ผลการศึกษา: *ผลการตรวจสมรรถภาพปอดจำนวน 1,556 ผล ถูกส่งมาจากเจ้าหน้าที่ผู้ทำการตรวจสมรรถภาพปอด 38 คน จากทั้งหมด 38 โรงพยาบาล ผลการตรวจประเมินพบว่ามีผลการตรวจสมรรถภาพปอดที่ผ่านการยอมรับ (acceptable) ตามมาตรฐานของสมาคมโรคทรวงอกแห่งอเมริกาและสมาคมโรคระบบการการหายใจแห่งยุโรปเพียง 1,066 ผล หรือ คิดเป็นร้อยละ 68.5 และมีเพียงร้อยละ 47.4 ของเจ้าหน้าที่คลินิกโรคปอดอุดกั้นเรื้อรังเท่านั้นที่มีผลการตรวจสมรรถภาพปอดผ่านเกณฑ์มาตรฐานมากกว่าร้อยละ 80 (เกรด A) จากผลที่ส่งมา โดยที่คุณภาพของผลการตรวจที่ได้เกรด A ทั้งหมดนั้นมาจากเจ้าหน้าที่ผู้ทำการตรวจสมรรถภาพปอดที่ผ่านการฝึกอบรมหรือรับรองจากสมาคมอุรเวชช์แห่งประเทศไทยแล้ว นอกจากนี้ยังพบว่าคุณภาพของผลการตรวจสมรรถภาพปอดที่ผ่านมาตรฐานการยอมรับนั้นจะสูงกว่าในเจ้าหน้าที่ที่ได้รับการฝึกอบรมหรือรับรองจากสมาคมอุรเวชช์แห่งประเทศไทย คือพบมากถึงร้อยละ 80.8 เมื่อเทียบกับผู้ที่ไม่ผ่านการอบรมหรือรับรองจากสมาคมอุรเวชช์แห่งประเทศไทยมาก่อนที่มีผลผ่านเพียงร้อยละ 18.2 (p-value <0.001) เกณฑ์การยอมรับซึ่งเจ้าหน้าที่ที่ผ่านการฝึกอบรมหรือรับรองจากสมาคมอุรเวชช์แห่งประเทศไทยสามารถทำได้สูงกว่าเจ้าหน้าที่ที่ไม่เคยผ่านการฝึกอบรมหรือรับรองมาก่อน ได้แก่ ระยะเวลาการเป่านานเพียงพอ (ร้อยละ 93.4 ต่อ ร้อยละ 20.9, p-value <0.001) ไม่หยุดเป่าหรือสูดหายใจกลับก่อนเวลาอันสมควร (ร้อยละ 98.5 ต่อ ร้อยละ 58.6, p-value <0.001) ความพยายามในการเป่าดีตลอดช่วงของการเป่าออก (ร้อยละ 96.2 ต่อ ร้อยละ 89.1, p-value <0.001) และเริ่มเป่าออกดีและแรงพอ (ร้อยละ 91.6 ต่อ ร้อยละ 79.9, p-value <0.001) เป็นต้น*

สรุป: *ผลการตรวจสมรรถภาพปอดในกลุ่มเจ้าหน้าที่ที่ผ่านการฝึกอบรมหรือรับรองโดยสมาคมอุรเวชช์แห่งประเทศไทยนั้นมีคุณภาพสูงกว่ากลุ่มเจ้าหน้าที่ที่ไม่ผ่านการฝึกอบรมหรือรับรองมาก่อน จากผลการศึกษานี้แสดงให้เห็นความสำคัญของการฝึกอบรมและการประเมินคุณภาพผลการตรวจสมรรถภาพปอดในเจ้าหน้าที่ผู้ทำการตรวจสมรรถภาพปอดในทางเวชปฏิบัติ*