Original Article

Quality of spirometry testing in a community setting: A study among elderly persons in a rural area of Haryana

Ravneet Kaur[1], Alok Kumar[1], Vijay Hadda[2], Kalaivani M[3], Baridalyne Nongkynrih[1], Shashi Kant[1], Sanjeev K. Gupta[1], Dwarakanathan Vignesh[1]

[1]Centre for Community Medicine, [2]Department of Pulmonary Medicine and Sleep Disorders, [3]Department of Biostatistics, All India Institute of Medical Sciences, New Delhi, India

Abstract

Introduction: Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide. Early diagnosis and management of COPD require good quality spirometry testing, which is currently not available at primary care level in India. This study reports the quality of spirometry testing at the community level among elderly persons in a rural area. **Materials and Methods:** A community-based cross-sectional study was conducted among 449 elderly persons in a rural area of Ballabgarh block of Haryana state by a trained investigator. A portable spirometer (MIR Spirolab®) was used. House-to-house visits were undertaken. A self-developed pretested semistructured interview schedule was administrated and spirometry was done according to the American Thoracic Society/European Respiratory Society (ATS/ERS) guidelines. **Results:** Acceptable quality of spirometry tests was found among 87.3% (95% CI: 84.2%–90.4%) participants. Poor quality of spirometry was associated with low Body Mass Index (BMI) (aOR = 0.49, 95% CI = 0.26–0.93) and age ≥ 70 years (aOR = 0.45, 95% CI = 0.21–0.94) in multivariable analysis. **Conclusion:** Acceptable quality of spirometry can be performed in community settings by using a portable spirometer.

Keywords: Community, elderly, quality, rural, spirometry

Introduction

Chronic respiratory diseases like chronic obstructive pulmonary disease (COPD) and asthma are important health problems in India. These diseases cause 10.9% of total deaths and contribute to 6.4% of all Disability Adjusted Life Years.[1]

As reported by the World Health Organization (WHO), COPD was the third leading cause of death in WHO-SEAR in 2015. Almost 90% of COPD deaths occur in low- and middle-income countries.[2] The magnitude of COPD is substantially higher among elderly persons.[3]

Worldwide, chronic respiratory diseases are under-diagnosed, and about two-thirds of the patients are never diagnosed even in developed countries.[4-6] Spirometry is an important investigation for early diagnosis and monitoring of patients with chronic respiratory morbidities. It is the most objective and reproducible measure of airflow limitation.[7] A high proportion of COPD in the community remains undiagnosed, as spirometry is under-used, particularly among elderly persons. In India, spirometry is available only at district-level health

Address for correspondence: Dr. Ravneet Kaur, Centre for Community Medicine, All India Institute of Medical Sciences, Ansari Nagar, New Delhi - 110 029, India.
E-mail: ravneetk08@gmail.com

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facilities or above. Access to spirometry at the level of primary care may help in early diagnosis, adequate management, and monitoring the progression of the disease. At the same time, quality of spirometry testing is an important concern. The patient is required to perform a number of rigorous breathing maneuvers, which require motivation and coaching by trained personnel. Therefore, the quality of spirometry tests is critically dependent on the skills of the operator and cooperation of the patient. This may be challenging in community settings, as compared to a laboratory. The results of previous studies conducted worldwide are inconsistent as to whether the quality of spirometry performed at the community level meets adequate minimum standards, especially among elderly persons.[8-11] In India, there is a paucity of studies on quality of spirometry testing in community settings. The present study was conducted among elderly persons in a rural area of Haryana and aimed to assess the quality of spirometry testing at community level.

Materials and Methods

This community-based, cross-sectional study was conducted in the rural field practice area of a research institute. The field practice area consisted of 28 villages in Ballabgarh block of Faridabad district of Haryana, and had a population of about 1,00,000 individuals, including nearly 7000 elderly persons. There is a computerized database of all individuals residing in the area, which is updated annually.

The study was conducted among elderly persons aged 60 years and above residing in the villages under field practice area for at least past 12 months.

Elderly persons who were seriously ill, unable to comprehend or had any contraindication to perform spirometry (any severe injury or surgery to abdomen, chest, or eye in last 3 months; myocardial infarction in last 3 months; hospitalization due to cardiac illness in last 30 days or were on treatment for tuberculosis) were excluded.

The sample size was calculated using the formula $4pq/d^2$. Because studies on the quality of spirometry in India were not available, proportion of persons getting acceptable results was assumed as 50%, and absolute error was taken to be 5%. Considering a nonresponse rate of 15% and migration of 5%, the sample size was increased to 500 elderly persons.

A list of persons aged 60 years and above was taken from the computerized database, and 500 participants were selected by simple random sampling using computer-generated random numbers.

Details of Spirometery

A portable spirometer MIR (Medical International Research) Spirolab® was used.[12] The spirometer complied with the ATS/ERS criteria for accuracy.[13] It was portable, had a long battery life, incorporated a quality assurance program, had an in-built printer, and it allowed the export of data. A single model of a spirometer was used for all participants.

Training

The investigator (AK) who conducted the spirometry tests was a medical graduate and was trained in the pulmonary laboratory of the research institute for 1 month (150 h) under the supervision of a faculty member of Department of Pulmonary Medicine and Sleep Disorders (VH), who had more than ten years of experience. During the training period, the investigator performed 50 spirometry tests, among patients of all age groups, with the assistance of a pulmonary laboratory technician, and 50 spirometry tests, without any assistance, among elderly patients in the pulmonary laboratory.

Quality assurance

The faculty member in Pulmonary Medicine (VH) was responsible for the training of the investigator and interpretation of results of spirometry tests, while the faculty in Community Medicine (RK) was responsible for supportive supervision in the field during house-to-house visits. Before data collection, the investigator performed the spirometry on elderly patients with the portable MIR Spirolab spirometer, and the findings of which were reconfirmed by the spirometer at the pulmonary laboratory of the research institute. All tests were read by the faculty for interpretation. The spirometer was calibrated at regular intervals.

Patient safety

The spirometry maneuver is generally safe. The primary risk associated with it is fainting among older participants with impaired lung function. To minimize the risk, spirometry was done in a seated position and the investigator was trained to watch for signs of dizziness or other problems and to stop the maneuver if necessary. The risk of infection was minimized by using single-use disposable mouthpieces. The testing was rescheduled to a later date for the participants with obvious upper respiratory infections.

Acceptability Criteria for Spirometry Test

Spirometry testing requires the participant to perform strenuous and precise physical maneuvers. The patient must inhale completely to total lung capacity, and without delay, blast the air from the lungs with maximum effort. The action must be maintained until the lung volume is near residual volume.

Recently published guidelines for spirometry by Joint Indian Chest Society-National College of Chest Physicians (India) have clearly stated within-maneuver acceptability criteria, between-maneuver repeatability criteria, and end of test criteria[14] In our study, these criteria were adhered to while performing spirometry, which was in compliance to ATS/ERS criteria as well.[13]

Thus, the following acceptability criteria were adhered to:
- A good start and satisfactory exhalation (in duration and flow)
- No cough during the first second of exhalation
- No abrupt termination
- Maximal effort provided throughout the maneuver
- No obstructed mouthpiece
- No leak
- No glottis closure that influences the measurement.

Quality of spirometry test as shown by spirometer and its interpretation based on acceptability and repeatability criteria[13,14]

Test Quality	Interpretation
A	At least three acceptable tests, with repeatability within 0.150 L
B	At least two acceptable tests, with repeatability within 0.150 L
C	At least two acceptable tests, with repeatability within 0.200 L
D	At least two acceptable tests, with repeatability within 0.250 L
E	One acceptable test
F	No acceptable test

** Participants were asked to repeat the test until Quality "A" results were obtained or the participant was exhausted, whichever was earlier.

Operational definitions

The following operational definitions were used in the study:

Chronic cough

Cough on most days for 3 consecutive months or more during the year for the past 2 years.[15]

Chronic phlegm

Phlegm on most days for 3 consecutive months or more during the year for the past 2 years or more.[15]

Dyspnea

Breathlessness while walking, which required the patient to stop or slow down for breathing while walking on the level.[15]

Recurrent wheeze

The occurrence of episodes of wheezing/whistling sounds in breathing associated with breathlessness at least once in a year for past 3 years.[16]

Ever smoker

A person who has smoked at least one cigarette/bidi per day for 1 year or more, or who has smoked hookah/chillum ≥10 times per month for 1 year or more.[17]

Never smoker

A person who has not smoked or who does not qualify in the definition of ever smoker.[17]

Body mass index (BMI)

It was calculated as Weight (in kg)/Arm span (in meter)^2 as arm span has been reported to be a more valid indicator of height among the elderly.[18]

BMI was categorized into -
1. Low (less than 18.5 kg/m^2)
2. Normal (18.5–24.9 kg/m^2)
3. High (25 kg/m^2 and above).

Acceptable quality test

Test quality A, B, C, and D were considered acceptable.

Unacceptable quality test

Test quality E and F were considered unacceptable.

Data Collection

House-to-house visits were undertaken. In case a participant was not found at home despite three visits, s/he was considered as a nonrespondent. All participants were provided with a participant information sheet, informed about the purpose of the visit, and written informed consent was taken. A pretested semistructured interview schedule was administered in Hindi; information was collected regarding sociodemographic details, history of chronic respiratory symptoms or respiratory disease, and smoking. Weight, height, and arm span were measured using standard techniques.[19] Among persons who were on regular treatment with bronchodilators, spirometry was done on the next day after asking them not to use bronchodilators for 24 h. For smokers, the spirometry test was done after 1 h of smoking free interval.

Spirometry was performed for the assessment of airway obstruction. The measurements were done using a hand-held portable spirometer (MIR Spirolab) according to the standard guidelines (American Thoracic Society/European Respiratory Society)[13] and Joint Indian Chest Society-National College of Chest Physicians (India) guidelines for spirometry.[14]

For each participant, information on weight and height was entered in the spirometer. The participant was asked to sit comfortably. Two measurements—one each of pre- and post-bronchodilator—were performed 20 min apart. Four puffs (100 mcg each puff) of salbutamol were administered via metered-dose inhaler with a double valve Volumatic spacer with a participant in seating position. Separate disposable mouthpieces were used for each participant. Prebronchodilator spirometry was performed in which the participants were asked to repeat the test until Quality "A" results were obtained or the participant was exhausted, whichever was earlier. After this, the participants were asked to inhale 4 puffs of 100 mcg each salbutamol through a metered-dose inhaler using a spacer device. Bronchodilator reversibility was undertaken on all patients, even if prebronchodilator lung function was within the normal range. Postbronchodilator spirometry was performed after a gap of 20 min of salbutamol inhalation. Again, participants were asked

to repeat the test until Quality "A" results were obtained or the participant exhausted, whichever was earlier.

Ethical Considerations

The study was conducted after obtaining ethical approval from the Ethics Committee of the research institute (Approval no. IEC-168 dated 25.08.2019). Participants who were found to have airway obstruction were referred to an appropriate health facility.

Statistical analysis

Data were entered in MS Excel 2013 and statistical analysis was carried out using Stata version 11 (College Station, Texas, USA). Sociodemographic profile and clinical profile were reported as mean (standard deviation) or number (percentage). Quality of spirometry was reported as number and percentage in each quality category. Quality categories A–D were included in acceptable quality, while quality category E and F were considered unacceptable. Respiratory symptoms were grouped and analyzed as persons with respiratory symptoms and persons without respiratory symptoms.

A multivariable logistic regression model was used to look for association between spirometry quality and other sociodemographic and clinical factors. First, bivariable logistic regression analysis was performed. Variables with *P* value < 0.25 were included in multivariable logistic regression model.

Results

Of total 500 randomly selected participants, one had died, three had migrated, while one participant was excluded due to rib fracture. Out of 495 eligible elderly, 44 participants were not available despite three visits, and two participants refused to give consent. Thus, the response rate was 90.7%.

The mean age of the 449 elderly participants was 68.6 years (SD = 6.8 years). Women constituted 57% of the study participants. Majority of the participants (75.5%) were illiterate, 63% belonged to lower-middle socioeconomic status, and 82.9% were married. Majority of the participants (93.3%) were economically dependent on care-providers. Nearly half (50.3%) of the participants were ever smoker. Nine persons (2% of participants) had a history of Antitubercular Treatment (ATT). Dyspnea was reported by 25.4% of the elderly, while 13.6% and 11.4%% of them reported chronic cough and chronic phlegm, respectively. For analysis, we grouped the persons with selected self-reported respiratory symptoms, and analyzed as respiratory symptoms present (n = 128, 28.5%) or absent (n = 321, 71.5%) [Table 1].

In our study, 87.3% of the participants were able to produce acceptable spirometry curve data. The majority were of spirometry quality A (n = 322, 71.7%). Remaining 57 (12.7%) participants could not produce acceptable quality of spirometry curve [Table 2].

In bivariable analysis, age, literacy, and BMI were significantly associated with quality of spirometry. On multivariable analysis, age more than or equal to 70 years and low BMI showed significant association. Odds of getting an acceptable quality of spirometry was 55% less likely among persons aged 70 years (aOR: 0.45, 95% CI: 0.21–0.94) and above compared to persons aged 60–64 years, and 50% less likely in elderly persons with low BMI (aOR: 0.49, 95% CI: 0.26–0.93) compared to normal BMI [Table 3].

Discussion

This study was undertaken in a rural setting among elderly persons. Pulmonary function tests are the most important investigation in the case of chronic respiratory disorders. Ability to perform spirometry in primary care settings benefits both patients, as they do not have to travel to the district hospital, and the health system, as the burden is reduced at the district level. However, obtaining good quality spirometry tests may be challenging in community settings. In our study, acceptable quality of spirometry tests was found among 87.3% (95% CI: 84.2%– 90.4%) participants. Unacceptable spirometry was associated with low BMI (aOR = 0.49, 95% CI = 0.26–0.93) and age ≥ 70 years (aOR = 0.45, 95% CI = 0.21–0.94). This finding is similar to some other community-based studies. Querioz *et al.* (2018) found acceptable results in 75.9% participants in a community-based study conducted among 255 elderly persons in Brazil. It was reported that older age and lower MMSE (Mini Mental State Examination) score were significantly associated with poor quality spirometry.[20] In a study by Belo *et al.* among 307 persons in elderly care centers in Lisbon in 2018, acceptable quality spirometry was present in 85.3%. The study followed the ATS criteria and spirometry was done by qualified and certified technicians.[21] Haynes assessed the ability to perform spirometry among elderly persons in a hospital in New Hampshire, England. The study reported that 94.6% of the elderly performed acceptable spirometry by ATS/ERS criteria.[22] This proportion is higher as compared to our study, which might be due to the fact that it was a retrospective review of hospital-based pulmonary function test (PFT) laboratory data. The study also reported that the quality of spirometry test results achieved by elderly persons was comparable to younger adults. Bellia *et al.* conducted a multicentric case-control study among elderly persons in twenty-four pulmonary or geriatric institutions, distributed throughout Italy, to assess the quality of spirometry among those with previously diagnosed respiratory morbidity (case), and those without previously diagnosed respiratory morbidity (control). Spirometry was done by trained staff. Acceptable spirometer readings were obtained in 83.6% cases and 81.9% controls. Stepwise logistic regression showed that lower performance was associated with lower activities of daily living score, lower MMSE score, and worse performance in the 6-min walk test. However, older age was associated with poorer FEV1 and FVC, but not poor spirometry performance.[23]

Older age and low BMI were associated with unacceptable spirometry results among the participants.[24] This finding is similar to our study, which suggests that spirometry might be

Table 1: Characteristics of study participants

Variables	Men *n*=193 (42.9%)	Women *n*=256 (57.1%)	Total *n*=449 (100%)
Age in (years)			
60-64	58 (30.1)	95 (37.1)	153 (34.1)
65-69	68 (35.2)	65 (25.4)	133 (29.6)
≥70	67 (34.7)	68.2 (6.6)	163 (36.3)
Literacy			
Illiterate	94 (48.7)	245 (95.7)	339 (75.5)
Literate	99 (51.3)	11 (4.3)	110 (24.5)
Socioeconomic status (*Udai-Pareek* socio-economic status scale)			
Lower	3 (1.6)	3 (1.2)	6 (1.3)
Lower middle	53 (27.5)	230 (89.8)	283 (63.0)
Middle	122 (63.2)	23 (9.0)	145 (32.3)
Upper middle	15 (7.7)	0 (0)	0 (0)
Marital status			
Married	160 (82.9)	146 (57.0)	306 (68.2)
Widowed/Single/separated	33 (17.1)	110 (43.0)	143 (31.8)
Economic dependence			
Independent	26 (13.5)	4 (1.6)	30 (6.7)
Dependent on care providers	167 (86.5)	252 (98.4)	419 (93.3)
Smoking status			
Never smoker	56 (29.0)	167 (65.2)	223 (49.7)
Ever smoker	137 (71.0)	89 (34.8)	226 (50.3)
History of ATT (Antituberculosis treatment)			
Absent	188 (97.4)	252 (98.4)	440 (98.0)
Present	5 (2.6)	4 (1.6)	9 (2.0)
Respiratory symptoms			
Absent	130 (67.3)	191 (74.6)	321 (71.5)
Present	63 (32.6)	65 (25.4)	128 (28.5)
[a]BMI (kg/m^2)			
Normal	93 (48.2)	143 (55.9)	236 (52.6)
Low	87 (45.1)	67 (26.2)	154 (34.3)
High	13 (6.7)	46 (18)	59 (13.1)

[a]BMI=Body Mass Index. For the purpose of analysis, all respiratory symptoms were combined and analyzed as present or absent

Table 2: Distribution of elderly persons by quality of spirometry test

Quality of spirometry test	Total (%) *n*=449	Age group (in years)	Men (%)	Women (%)	Total (%)
*Acceptable quality (A-D)			**174 (90.2)**	**218 (85.2)**	**392 (87.3)**
Quality A	332 (71.7)	60-64	46 (79.3)	74 (77.8)	120 (78.4)
		65-69	52 (76.4)	45 (69.2)	97 (72.9)
		≥70	40 (59.7)	65 (67.7)	105 (64.4)
Quality B	24 (5.3)	60-64	3 (5.1)	5 (5.2)	8 (5.2)
		65-69	5 (7.3)	3 (4.6)	8 (6.0)
		≥70	5 (7.4)	3 (3.1)	8 (4.9)
Quality C	13 (2.9)	60-64	2 (3.4)	2 (2.1)	4 (2.6)
		65-69	1 (1.4)	2 (3.0)	3 (2.2)
		≥70	3 (4.4)	3 (3.1)	6 (3.6)
Quality D	33 (7.3)	60-64	4 (6.8)	4 (4.2)	8 (5.2)
		65-69	5 (7.3)	6 (9.2)	11 (8.2)
		≥70	8 (11.9)	6 (6.2)	14 (8.5)
Unacceptable quality			**19 (9.8)**	**38 (14.8)**	**57 (12.7)**
Quality E and F		60-64	3 (5.1)	10 (10.5)	13 (8.4)
		65-69	5 (7.3)	9 (13.8)	14 (10.5)
		≥70	11 (16.4)	19 (19.7)	30 (18.4)

*Spirometry test quality A-D were considered together as acceptable quality. There was no significant difference in test quality among men and women chi-square = 2.48 *P* value = 0.12

challenging in frail elderly persons. The study also suggested that unacceptable curves might still be clinically useful, as FEV_1/FEV_6 was shown to have reproducible results and good correlation with FEV_1/FVC among elderly persons.[24]

Table 3: Factors associated with acceptable quality spirometry test

Variables	Number (*n*=449)	Acceptable test quality (*n*=392)	Unadjusted OR (95% CI)	*P*	Adjusted OR (95% CI)	*P*
Age in (years)						
60-64	153	140 (91.5)	Reference		Reference	
65-69	133	119 (89.5)	0.79 (0.36-1.75)	0.559	0.74 (0.32-1.67)	0.465
≥70	163	133 (81.6)	0.41 (0.21-0.82)	0.012	0.45 (0.21-0.94)	0.034
Gender						
Women	256	218 (85.2)	Reference		Reference	
Men	193	174 (90.2)	1.60 (0.89-2.87)	0.118	0.32 (0.03-3.08)	0.323
Literacy						
Illiterate	339	288 (85.0)	Reference		Reference	
Literate	110	104 (94.6)	3.07 (1.28-7.36)	0.012	2.60 (0.82-8.25)	0.104
Socioeconomic status						
High	160	146 (91.3)	Reference		Reference	
Low	289	246 (85.1)	0.55 (0.29-1.04)	0.065	1.05 (0.43-2.57)	0.913
Marital status						
Married	306	272 (88.9)	Reference		Reference	
Widowed/Single/separated	143	120 (83.9)	0.65 (0.37-1.15)	0.142	1.05 (0.55-2.05)	0.882
Economic dependence						
Independent	30	29 (96.7)	Reference		Reference	
Dependent on care providers	419	363 (86.6)	0.47 (0.1701.29)	0.145	0.72 (0.23-2.22)	0.564
Smoking status						
Never smoker	223	195 (87.4)	Reference		Reference	
Smoker	226	197 (87.2)	0.98 (0.56-1.70)	0.930	NS	NS
History of ATT						
Absent	440	385 (87.5)	Reference		Reference	
Present	9	7 (77.8)	0.5 (0.10-2.47)	0.395	NS	NS
Respiratory symptoms						
Absent	321	276 (86.0)	Reference		Reference	
Present	128	116 (90.6)	1.58 (0.80-3.09)	0.185	1.70 (0.84-3.45)	NS
BMI (kg/m^2)						
Normal	236	212 (89.8)	Reference		Reference	
Low	154	127 (82.5)	0.53 (0.29-0.96)	0.037	0.49 (0.26-0.93)	0.030
High	59	53 (89.8)	1.00 (0.39-2.57)	1.000	0.98 (0.37-2.58)	0.971

NS=Nonsignificant

In a study by Turkeshi *et al.* among two primary care cohorts of community-dwelling elderly in Russia and Belgium, spirometry tests of acceptable quality as per ATS/ERS criteria could be achieved by 43.3% and 57.7% of the elderly persons, respectively. The low percentage of acceptable quality tests may be because elderly of age 80 years or more were studied. Female sex, lower education, depression, and lower MMSE score were reported to be associated with poor quality spirometry. However, the study concluded that impaired cognition measured by MMSE may not be an independent predictor of poor-quality spirometry, even among those who were over 80 years old, and recommended that spirometry should be used more often among the elderly in primary care settings.[25]

Earlier research has highlighted that spirometry in primary care setting avoids waiting time for testing at hospital laboratories, is more convenient to the patients, and also provides timely data to physicians. It can be a viable option at primary health care level provided that it operates under appropriate quality assurance guidelines. The position statement developed by the Canadian Thoracic Society (2013) provided guidance on key factors affecting the quality of spirometry testing in primary care settings. It was recommended that the equipment used should be standardized and the person conducting the test should be appropriately trained. Moreover, interpretation of the tests should be done by an expert.[26]

In their study on the establishment of community-based spirometry service in the Canterbury region of New Zealand, Epton *et al.* showed that laboratory-quality spirometry can be carried out in the community. They also highlighted the need for adequate training and monitoring of quality assurance to achieve acceptable quality spirometry testing.[27]

In a study conducted among persons at risk of developing COPD in primary care settings of Tasmania, it was reported that early diagnosis of COPD increased with the provision of spirometry testing, performed according to the standard guidelines for quality assurance. The study also concluded that assistance in the form of interpretation of tests by experts is required in such settings.[28]

Primary care settings are usually the first point of contact for patients, particularly in rural areas. Respiratory symptoms such as

cough, wheezing, shortness of breath as well as conditions like follow-up of asthma and COPD are among the top-20 reasons for which patients consult a doctor in primary care practice in India.[29] Symptom-based diagnosis of COPD in primary care may be unreliable and leads to inappropriate management of the disease.[30]

It is been reported that a high proportion of patients of COPD are not diagnosed correctly until they reach tertiary care health facilities. A study conducted in Kerala reported that out of 129 patients of COPD diagnosed at a tertiary care hospital, only one had been diagnosed earlier.[31] Hence, good quality spirometry is essential at the level of primary health care, in order to make an early and accurate diagnosis of COPD, which will lead to appropriate management of disease at an early stage.

A recently published report of the Global Initiative for Chronic Obstructive Lung Disease (GOLD 2019) has suggested that good quality spirometry measurement is possible in any health care setting and all professionals who treat patients of COPD should have access to good quality spirometry.[7]

In our study, spirometry testing was done as per the standards for acceptability and repeatability. The investigator received appropriate training at the PFT laboratory, and interpretation of the test results was done by an expert.

However, our study had few limitations. Cognitive impairment was not measured by MMSE scores. Hence, the association of poor cognition with quality of spirometry test could not be assessed. In our study, persons who were not able to comprehend the questions during the interview were proposed to be excluded from the study. However, we did not come across any such participant.

Spirometry testing was done by a medical graduate who was trained to conduct spirometry and was supportively supervised during training as well as during house-to-house visits. The same may not be feasible in other settings.

High response rate and good quality control were major strengths of our study. The investigator was duly trained and the instrument was standardized.

Conclusion

Acceptable quality of spirometry can be achieved among the elderly at the level of primary care by using a portable spirometer. However, it requires comprehensive training and monitoring of quality assurance. The costs of training, equipment, and quality assurance may prove to be potential barriers for providing spirometry testing services at primary care settings.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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