



THE UNDERUSE OF SPIROMETRY IN ROUTINE MEDICAL PRACTICE FOR DIAGNOSIS AND MANAGEMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) PATIENTS IN KARACHI, PAKISTAN

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ABSTRACT

Introduction: Spirometry is important in the diagnosis and management of chronic obstructive pulmonary disease (COPD), yet it is a common clinical observation that it is underused though the extent is unclear. This survey aims to examine the use of spirometry in the diagnosis and management of COPD patients in districts of, Karachi. **Material and Methods:** It is a cross-sectional survey involving four clinic settings: hospital-based respiratory specialist clinic, hospital-based mixed medical specialist clinic, general outpatient clinic (primary care), and tuberculosis and chest clinic. Thirty physician-diagnosed COPD patients were randomly selected from each of the four clinic groups. All of them had a forced expiratory volume in 1 second (FEV₁) to forced vital capacity (FVC) ratio less than 0.70 and had been followed up at the participating clinic for at least 6 months for COPD treatment. **Results:** Of the 120 COPD patients, there were 111 males and mean post-bronchodilator FEV₁ was 46.2% predicted. Only 22 patients (18.3%) had spirometry done during diagnostic workup, and 64 patients (53.3%) had spirometry done ever. **Conclusion:** We conclude that spirometry is underused in general but especially by non-respiratory physicians and family physicians in the management of COPD patients. More effort at educating the medical community is urgently needed.

KEYWORDS: Pulmonary function tests, Specialist, Forced expiratory volume in 1 second (FEV₁), Forced vital capacity (FVC).

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is characterized by advancing airflow obstruction and impairment of gaseous exchange resulting in progressive worsening of shortness of breath. The disease affects 65 million people worldwide and more than 12 million people in the US alone, and is likely that these figures are grossly underestimated.^[1-3] More than three million people died from COPD in 2005, and it is predicted that mortality from this disease will continue to increase.^[2] In Pakistan, the burden of COPD is also high, with high utilization of health care resources.^[4-6]

Diagnosis of COPD rests on history, physical examination, chest radiograph, and the demonstration of airflow obstruction

by spirometry. Although being criticized as overly simplistic,^[7,8] the spirometric finding of a post-bronchodilator forced expiratory volume in 1 second (FEV₁) to forced vital capacity (FVC) ratio of less than 0.70 is still universally accepted as being diagnostic of significant airflow obstruction.^[1,9-11] Having made the diagnosis, one would like to assess the severity of the disease. Percentage predicted post-bronchodilator FEV₁ is objective and reproducible, correlates well with disease severity, and is a good prognostic indicator.^[12, 13] Furthermore, in the subsequent management of COPD, serial FEV₁ can serve to follow the progress of the disease and provide guidance on treatment options in different stages of disease evolution.

It is therefore hardly surprising that all the major international COPD management guidelines mandate the use of spirometry in the initial diagnostic evaluation of patients with symptoms suggestive of COPD.^[1,10,11,14] However, it is a common observation in daily clinical practice that spirometry is very much underused. In fact, it is not uncommon for patients with severe COPD to have the disease diagnosed and treated for many years, yet have no spirometry done. To examine the extent of the problem, we set out to conduct a survey to observe the use of spirometry in COPD management.

MATERIALS AND METHODS

The objective of the survey was to observe what investigations and treatments COPD patients actually receive

This is a cross-sectional survey carried out in Lyari and Garden areas of Karachi, with a population of approximately 616,151.

There were a total of eleven secondary level clinics or health centers in the private and public sector which care for COPD patients in the area under study. COPD patients had long-term follow-up. The clinics or health centers were grouped according to their specialty, and 30 COPD subjects were selected from each group: group 1, one respiratory specialist clinic or health center; group 2, four general medical specialist clinics or health centers; group 3, five family medicine clinics or health centers or general outpatient clinics or health centers (primary care clinics); group 4, one tuberculosis and chest clinics or health centers.

For groups 1–3, subject lists were generated from the hospital Data Analysis and Reporting System in June 2014. Subjects were randomly selected from the list and were invited to participate in the study by phone call. An appointment was given to verbally consenting subjects to attend a study visit. Recruitment for each group stopped when 30 consenting and evaluable subjects for that group has been accrued. For group 4, since no patient list could be generated, COPD subjects were invited to participate in the study as they attended follow-up at the clinic; workflow was similar to the other groups.

At the study visit, subjects signed an informed consent form and were then checked for study entry criteria. Inclusion criteria

were: (1) physician-diagnosed COPD, (2) post-bronchodilator FEV₁ to FVC ratio less than 0.70 (3) regular follow-up at the participating clinic for treatment of stable COPD for at least 6 months, and (4) willing and able to comply with study requirements such as performing spirometry and 6-minute walk test. Exclusion criteria were: (1) non-COPD diagnosis as judged by the investigator; (2) subjects attending regular follow-up at another clinic and attending the participating clinic irregularly for acute exacerbation of COPD or other problems; (3) history of significant coexisting chronic lung disease such as asthma, pulmonary fibrosis, bronchiectasis, and restrictive lung disease; and (4) history of lung resection.

When the subjects satisfied all inclusion and none of the exclusion criteria, collection of demographic data, medical data, and smoking history was done. The use of spirometry in the diagnosis and subsequent management of COPD were recorded from the medical records and word of mouth was not accepted. Use of spirometry for diagnostic workup is defined as spirometry done within 6 months before or after making the COPD diagnosis. If the subject had spirometry done in the study center within the previous year, the result was used for study analysis, otherwise spirometry was done for all subjects during the study visit. This was done according to American Thoracic Society/European Respiratory Society 2012 recommendations,^[15] and the subject must not have had COPD exacerbation in the preceding four weeks. Local reference values were used for FEV₁ and other spirometric parameters.^[16] Measurement of body mass index; 6-minute walking distance,^[17] and dyspnea level using the Medical Research Council dyspnea scale^[18] were also done.

After the study visit, subjects continued to attend regular follow-up at their original clinic. Summaries of a subject's clinical findings and/or treatment recommendations were supplied to the care giver on request.

Data were expressed as percentages, means, and medians, as appropriate. During univariate analysis to compare variables between the groups with and without spirometry ever performed, independent-samples *t*-test, Mann–Whitney *U*-test, and chi-square test were used as appropriate. If there was at least

one group with expected count less than 5 when comparing distributions, Fisher's exact test was used. McNemar's test was used to compare the proportion of patients with spirometry and/or chest radiograph done at diagnosis/ever because the samples were deemed related. With the same standpoint, mean time before study visit of spirometry and chest X-ray were compared by *t*-test for two related samples. Those variables with *P*-value less than 0.2 in univariate analysis were subject to logistic regression by backward elimination method, with "significant level of stay" set to 0.10. A *P*-value of less than 0.05 was considered statistically significant.

The study was approved by the Research Ethics Committee of Shaheed Mohtarma Benazir Bhutto medical college Karachi and the Ethics Committee of the Department of Health.

RESULTS

Subject recruitment started in June 2014 and was completed in November 2014. A total of 144 subjects were invited to participate in the study. Fourteen subjects refused to participate; two were excluded because of concomitant lung disease, and one died before attending a study visit. The remaining 127 subjects attended study visits. Seven were excluded because the diagnosis was judged to be non-COPD on basis of spirometry.

Finally, the data of 120 subjects with 30 from each clinic group were analyzed (Table 1).

For the six subjects who were excluded during study visits for non-COPD diagnosis, all had a FEV₁ to FVC ratio greater than 0.70, and five had a post-bronchodilator FEV₁ percentage predicted higher than 80%. Three had chronic bronchitic symptoms and were given the diagnosis of "bronchitis not otherwise specified," one had mild bronchiectasis, which could explain the symptom of chronic productive cough, while one had no bronchitic symptoms and was considered free from lung disease. The remaining female subject had a very low post-bronchodilator FEV₁ of only 40% predicted, and she likely suffered from interstitial lung disease.

For the final 120 subjects, males predominated (111, 92.5%), and mean age was 71.8 years. All were local residents and all but six were either current or ex-smokers. Mean post-bronchodilator FEV₁ was 46.2% predicted, and stratification into Global Initiative for Chronic Obstructive Lung Disease (GOLD) stages I was: stage I, 10 (8.3%); stage II, 38 (31.7%); stage III, 46 (38.3%); and stage IV, 26 (21.7%). Other characteristics are shown in Table 2 & 3.

Table: 1. Subject Screening and Recruitment Summary

Total No of Patients (n=144)	GROUP 1 Respiratory Specialist Clinics (n=37)	GROUP 2 General Medical Clinics (n=35)	GROUP 3 General Out Patient Clinics (n=37)	GROUP 3 Tuberculosis and Chest Clinics (n=35)
No of Patients attended the study (n=127)	30	32	34	31
No of Patients refused to attended the study (n=17)	7	3	3	4
No of Patients excluded on basis of spirometry (FEV ₁ /FVC=>0.80%) (n=7)	Nil	2	4	1
No of patients finally attended the study (n=120)	30	30	30	30

n: Number of patients FEV₁: Forced expiratory volume in first second, FVC: Forced vital capacity.

Table 2. Subject characteristics according to whether spirometry was ever performed

PARAMETER	ALL (n=120)	WITH SPIROMETERY (n=64)	WITHOUT SPIROMETERY (n=56)	p-Value
Male : Female	111 : 9	58 : 6	53 : 3	-----
Male %	92.5%	90.6%	94.6%	0.500 ^a
Age (mean, SD)	71.8 (8.02)	71.7 (7.04)	71.9 (8.82)	0.883 ^b
SMOKING STATUS:				
Never (n, %)	6(5%)	4(6.3%)	2(3.6%)	----
Ex (n, %)	88(73.3%)	48(75.0%)	40(71.4%)	----
Current (n, %)	26(21.7%)	12(18.8%)	14(25%)	0.407 ^c
Pack / Year(mean, SD)	58.4(37.90%)	59.2(36.46%)	57.6(39.45%)	0.226 ^d
Worker occupation (n, %)	70(58.3%)	38(59.4%)	32(57.1%)	0.805 ^c
With old PTB (n, %)	20(16.7%)	5(7.6%)	15(26.8%)	0.005 ^c
^c Significant Medical Morbidity At least one (n, %)	72(60.0%)	38(59.4%)	34(60.7%)	0.881 ^c
Duration of COPD in years (mean, SD)	9.8 (7.55)	9.6 (6.18)	10.1 (8.86)	0.431 ^d
Post BD FEV1 %age predicted (mean/SD)	46.2 (19.89)	41.0 (17.57)	52.1 (20.72)	0.022 ^d
Post BD FVC %age predicted (mean/SD)	71.7 (22.86)	66.6 (26.62)	77.5 (24.07)	0.027 ^d
Peak expiratory ratio (FEV1/FVC) (mean/SD)	0.476 (0.131)	0.455 (0.126)	0.499 (0.133)	0.067 ^d
FEV1 BD reversability (mean, SD)				
Volume Change (ml)	122.5 (124.1)	104.8 (113.9)	142.7 (133.0)	0.145 ^d
Percentage change	5.5 (5.5)	4.8 (5.0)	6.4 (5.9)	0.137 ^d

^a Fischer's exact test, ^bIndependent sample t-test, ^c Chi square test, ^d Mann-Whitney U test, ^e

Significant medical comorbidity includes hypertension, ischemic heart disease, congestive heart failure, cardiac arrhythmia, cerebrovascular disease, diabetes mellitus with or without complications, chronic liver disease, chronic renal disease, obstructive sleep apnea, rheumatoid arthritis, tumors, malignancies, depression, and schizophrenia. **SD**, standard deviation; **PTB**, pulmonary tuberculosis; **COPD**, chronic obstructive pulmonary disease; **post-BD**, post-bronchodilator; **FEV₁**, forced expiratory volume in 1 second; **FVC**, forced vital capacity;

Table 3. Subject characteristics according to whether spirometry was ever performed

PARAMETER	ALL (n=120)	WITH SPIROMETRY (n=64)	WITHOUT SPIROMETRY (n=56)	p-Value
GOLD Stage (n, % of group, 95% CI)				
Stage I	10	2(20%, 4.8-44.8%)	08 (80%)	0.003 ^a
Stage II	38	15(39.5%, 24-55%)	23(60.5%)	
Stage III	46	27(58.7%, 44.5-72.9%)	19(41.3%)	
Stage IV	26	20(76.9%, 60.7-93.1%)	06(23.1%)	
BMI (mean, SD)	22.2(3.84)	22.4(3.56)	22.1(4.13)	0.479 ^d
6 MWD in meters (median, SD)	253.7(77.20)	256.7(77.53)	250.2(76.68)	0.650 ^b
MRC dyspnea score (median, IQR)	2(1)	2(1)	2(1)	0.941 ^d
CLINIC LOCATION				
Respiratory Specialist Clinic (group 1)	30	29(96.7%)	1(3.3%)	0.000 ^c
Medical Specialist Clinic (group 2)	30	20(66.7%)	10(33.3%)	
Primary Care Clinic (group 3)	30	08(26.7%)	22(73.3%)	
Tuberculosis and Chest Clinic (group 4)	30	07(23.3%)	23(76.7%)	
Group 2+3+4	90	35(38.9%)	55(61.1%)	

Fischer`s exact test, ^bIndependent sample t-test, ^c Chi square test, ^d Mann-Whitney U test,

GOLD, Global Initiative for Chronic Obstructive Lung Disease; BMI, body mass index; 6 MWD, 6-minute walking distance; MRC, Medical Research Council; CI, confidence interval; IQR, interquartile range.

Table 4. Factors associated with spirometry ever done – multivariate analysis (logistic regression by backward elimination).

PARAMETERS	ADJUSTED ODD'S RATIO	95% CI	P -Value
With old PTB	0.138	(0.026-0.726)	0.019
Clinical locations (compared with group 1)			
Group 2	0.049	(0.005-0.4720)	0.009
Group 3	0.009	(0.001-0.092)	0.000
Group 4	0.008	(0.001-0.080)	0.000
GOLD stage (compared with stage 1)			NS
Post BD FEV ₁			NS
%age predicted post BD FVC			NS
%age predicted peak expiratory ratio (FEV ₁ /FVC)			NS
FEV ₁ BD reversibility change (ml)			NS
FEV ₁ BD reversality change (%)			NS

CI, confidence interval; GOLD, Global Initiative for Chronic Obstructive Lung Disease; post-BD, post-bronchodilator; FEV₁, forced expiratory volume in 1 second; FVC, forced vital capacity; NS, non-significant.

Table 5. Comparison of use of spirometry and chest radiograph

PARAMETERS	SPIROMETRY	CHEST RADIOGRAPH	Pvalue
Done at Diagnosis	22 (18.3%)	96 (80%)	0.000 ^a
Done Ever	64 (53.3%)	117 (97.5%)	0.000 ^b
Mean time before study	39.1	12.1	0.000 ^b
Visit (months)	-	-	-
Range (months)	1 - 132	0.5 - 84.0	NA

^aMcNemar's test; ^bt-test for two related samples; NA, not applicable.

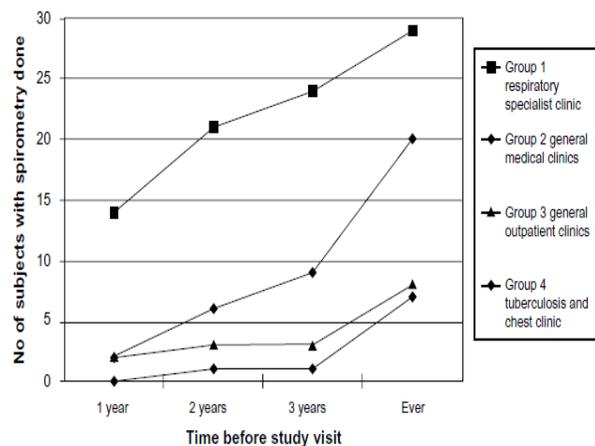
Sixty-four subjects (53.3%) had spirometry ever done prior to study visit and 56 subjects did not. Table 2 and 3 presents data comparing demographic and medical data of the two groups. By univariate analysis, factors significantly associated with spirometry ever done were absence of old pulmonary tuberculosis, more severe disease (lower post-bronchodilator FEV₁ percentage predicted and more severe GOLD stage), post-bronchodilator FVC percentage predicted, and clinic group 1 (versus groups 2, 3, and 4 combined). All other factors did not show statistically significant differences between the two groups. These include age, sex, smoking status, number of pack-years, former worker occupation, presence of significant comorbidities, duration of COPD, body mass index, exercise capacity (6-minute walking distance), and severity of dyspnea (Medical Research Council dyspnea score).

In the subsequent multivariate analysis (Table 4), absence of old pulmonary tuberculosis and clinic group 1 significantly favored spirometry ever done, whereas GOLD stage, post-bronchodilator FEV₁ percentage predicted, post-bronchodilator FVC percentage predicted, peak expiratory ratio (FEV₁/FVC), and FEV₁ bronchodilator reversibility change in volume and percentage were not.

Table 5 shows the use of spirometry compared with chest radiograph, which is another important investigation in the management of COPD. Overall, spirometry was performed in only 22 subjects (18.3%) during diagnostic workup, and 64 subjects (53.3%) had it ever done. For those who had spirometry ever done the mean time interval before study visit was 39.1 months, with a range of 1–132 months. By contrast, chest radiograph was done at diagnostic workup in 96 subjects (80%) and was ever done in 117 subjects (97.5%). Mean time of last order of chest radiograph prior to study visit was much shorter at 12.1 months, with a range of 0.5–84.0 months. All the differences were highly statistically significant.

The timeframe of performing spirometry prior to study visit is depicted in Graph 1. The Graph shows that at all time points, group 1 had a higher proportion of patients having spirometry performed compared with the other groups. Of note is that within 2 years preceding the study visit, 21 subjects (70%) in

group 1 had spirometry done, whereas values for groups 2, 3, and 4 were 6 (20%), 3 (10%) and 1 (3.3%) respectively.



DISCUSSION

To our knowledge this is the first cross-sectional survey to examine the use of spirometry in the management of diagnosed COPD patients in Karachi. Our data shows that only 18.3% of COPD patients in various districts had spirometry done at diagnosis and 53.3% had it ever done, indicating inconsistent use. Interestingly, this problem appears to be commonplace across the world. A Swedish survey found that of 533 newly diagnosed COPD patients, 59% had spirometry performed and 45% had post bronchodilator spirometry values. An FEV₁ to FVC ratio of less than 0.70 was found in only 30% of patients.^[19] The Canadian CAGE study involving 1,090 COPD patients from Quebec and Ontario found that 56% had spirometry ever done.^[20] In the People's Republic of China, a large survey involving 20,245 COPD subjects from seven provinces/cities showed that only 6.5% were tested with spirometry.^[21] A recent audit of the US Veterans Health Administration involving 93,724 newly diagnosed COPD patients found that only 36.7% had spirometry performed 2 years before or 6 months after the diagnosis was made.²² This was despite the (then) recent inclusion of this investigation as a performance measure by the United States National Committee for Quality Assurance.^[22]

When we tried to look for factors that favor performance of spirometry, we found as expected that clinic location is the most important factor. This finding suggests that patient factors were not responsible for alerting a doctor to order spirometry in

COPD management. Rather, the medical specialty appear to be the important factor, with respiratory physicians most inclined to order spirometry followed by general physicians followed by primary care physicians and tuberculosis and chest physicians. Similar findings were reported by Lee et al,^[23] in which use of spirometry for newly diagnosed COPD patients was 3.3 times higher for those visiting pulmonologists compared with those visiting primary care alone. One possible explanation for these findings is that patients followed up at respiratory specialist clinics have more severe disease, but statistical analysis of our data has indicated that disease severity is not an important factor in this regard. A more plausible explanation might be that specialization towards respiratory medicine increases awareness of the need for spirometry and the proficiency in interpreting the spirometry results. Overseas surveys have observed that use of office spirometry is associated with many practical problems, including availability of spirometer and space, need for calibration and standardization of the spirometer,^[24] and availability of adequately trained staff.^[25] Confidence in interpretive skills appears to be an important factor in primary care^[26] and was not improved by computerized expert report systems.^[27] Chest radiograph on the other hand is readily available and routinely reported by radiologists, and its higher utilization compared with spirometry may lend support to the above speculation.

A surprise finding is the significant association of the presence of old pulmonary tuberculosis with lack of spirometric assessment. There have not been similar reports elsewhere, and the cause for this finding is not immediately obvious. One would have thought that old pulmonary tuberculosis should be an additional prompt for doctors to order spirometry since there is another lung pathology on top of COPD. However, if doctors can ignore factors like smoking status, significant dyspnea, and poor exercise tolerance, old pulmonary tuberculosis as a prompt to order spirometry may not be a realistic expectation.

Damarla et al^[28] reported in a retrospective study that of patients admitted to hospital over an 8-year period, only 31% of COPD patients (36% with concomitant respiratory failure) had spirometry done, whereas 78% had two-dimensional echocardiography done for patients with congestive heart

failure. For the 219 patients with both conditions, 48% had two-dimensional echocardiography as the only confirmatory test, 34% had both tests performed, and only 2% had spirometry alone. The result is disturbing, since the two tests are very comparable in availability, complexity, ease of interpretation, and utility for treatment guidance. These findings once again suggest that physicians are insufficiently informed on the importance of spirometry in COPD management.

It would appear then that educational workshops with information on the indications, interpretation, and implications of spirometry results, and hands on workshops on lung function testing may contribute towards solving the current problem. Some published reports focusing on primary care show good short-term results,^[29, 30] but longer-term improvements remain to be seen. Published reports on spirometry workshops with a wider medical audience are lacking. On a different front, spirometry campaigns such as the 2010 World COPD and Spirometry Day may also be useful in increasing public awareness, putting pressure on the medical community to use the test appropriately and consistently. Finally, the setting up of incentive systems like the Quality and Outcomes Framework for general practitioners in the United Kingdom is likely to be helpful.

Our study has the strength that subjects are enrolled from different clinic types, which allows comparisons between them. Also, unlike surveys based on diagnostic and procedural coding, all of our subjects attended a study visit and had clinical and spirometry assessment done to confirm the diagnosis of COPD and whether spirometry was done.

Previously the study is however limited by its relatively small sample size and its limited location in Garden/Lyari. Larger, territory-wide studies would be able to give more precise information on the overall situation. Another limitation is the small proportion of female subjects, which probably reflects the low prevalence of smoking amongst women and which severely limits the applicability of our results to this gender.

CONCLUSION

In conclusion, spirometry is inconsistently used in the management of COPD in Garden/Lyari region, Karachi, with

most of the problem being seen in non-respiratory and primary care clinics. A combination of monitoring systems on the use of spirometry in COPD, more education on the importance of spirometry in COPD management, and assistance in interpretation of spirometry results may bring about improvements.

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