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NORMATIVE SPIROMETRIC VALUES AND PREDICTION EQUATIONS IN HEALTHY NON-SMOKING ADULT POPULATION OF WEST BENGAL.

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ABSTRACT

Background: Normative values of spirometric data in eastern Indian population need to be revisited. On this background the present study is aimed to determine the normal spirometric data and to generate prediction equations in young healthy non-smoking adults of eastern India.

Methods: The spirometric values, estimated by electronic spirometer, model-RMS Helios-702 in the Department of Physiology, R.G.Kar Medical College, Kolkata on 1563 subjects were analysed for the present study.

Results: Spirometric variables (FVC, FEV1, and FEV1/FVC) have significant positive correlations with height, and significant negative correlation with age. Regression equations have been computed to predict spirometric variables from age and body height.

Conclusion: Normative values and prediction equations for spirometric data was found to be mostly unchanged in Eastern India after two decades.

KEYWORDS : FEV1, FVC, Prediction Equation, West Bengal,

Introduction

Spirometry, the most common test for lung function, has an important role in screening, diagnosing and monitoring respiratory functions in different conditions and diseased states[1] and also helps in evaluation of breathing reserve and exercise tolerance to determine physical fitness in normal people[2]. It is a fact that from history and physical examination alone physicians cannot identify obstructive or restrictive patterns of respiratory diseases reliably[3] and this needs spirometry. Spirometry in addition can quantify severity and presence of reversible component of airflow obstruction. In Framingham study [4] decrease in vital capacity was a better predictor of heart failure and recovery than symptoms and signs. Regarding the role of pre-operative spirometry the goals are now clearly defined[5]. Screening and monitoring are necessary for cigarette smokers and people exposed to agents known to cause lung injury[6].

Quality is important concern in lung function testing in view of greater variability than most other laboratory tests. High quality test results can be achieved by accurate equipment, good test procedures, appropriate reference values, ongoing quality control, and good algorithm for the interpretation of results by comparing with values from healthy population.

In most other measurements in medicine universally applicable normal ranges are available, but lung function parameters shows wide variations even in normal. The American Thoracic Society (ATS), European Respiratory Society (ERS) and others have published standard designs to minimise the variability in these tests[7,8]. Besides technical factors related to equipment and procedures, biological and environmental factors are other sources of variation. These include age, sex, height, physical activity, smoking, environmental conditions, ethnicity, socio-economic status, altitude and other undefined factors[9]. The wide range of geographical and climatic conditions in a large country such as India may be associated with regional differences in lung function in healthy individuals, as shown in previous studies[10].

Several prediction equations have been described for western, eastern, northern, and southern regions in India[10-14]. These equations have limitations. Most of these are two or more decades old and have been carried out using different equipments and different methodologies.

On this background this study was designed with an aim to compute the spirometric data of normal population and to generate prediction equations from this data on eastern Indian population.

Aims and objectives:

1. To derive normative spirometric values and prediction equations in adult non smoker eastern Indian population.
2. To find out the association of spirometric values with age, sex and height.

Methodology

Spirometric data obtained from subjects tested in the Pulmonary Function Laboratory of the Physiology Department, R.G.Kar Medical College, Kolkata, over a period of one year from March 2012 to July 2014, were considered for inclusion in this retrospective study. Out of 3200 test results, 1563 were included in the present study following inclusion and exclusion criteria. Written informed consent from every subject was taken before performing the test. Approval was granted by the Ethics committee of R.G. Kar Medical College, Kolkata, India.

Experimental Protocol: Subjects were selected from the participants, referred to the pulmonary function laboratory in the Physiology Department by a variety of medical specialties including General Medicine, Chest Medicine, General Surgery, Pediatrics, Gynecology, Oncology, etc. The treatment sheets of all the subjects were consulted for their relevant history so also for the pulmonary functions test results. The essential inclusion criteria were (i) the performance of acceptable spirometry manoeuvre as per the ATS and European Respiratory Society (ERS) recommendations[15], (ii) subjects were 15 to 50 years of age, (iii) apparently healthy (iv) spirometric values considered: FVC ≥ 80% of predicted, FEV1 ≥ 80% of predicted, FEV1/FVC ≥ 70% of predicted.

The following subjects were excluded from the study: (i) history of chest trauma; tobacco smoking; exposure to substances known to cause lung injury i.e., asbestos, silica, cotton dust, coal, etc.; (ii) professions, such as, stone crushers, wood workers, cotton dust workers, pigeon breeders etc.; (iii) known to have other diseases such as bronchial asthma, chronic obstructive pulmonary disease, pulmonary tuberculosis, pneumonia, chronic bronchitis, emphysema, hypertension, heart failure, diabetes mellitus or any other abnormality (iv) abnormal chest radiograph and electrocardiogram (ECG); and (v) use of diuretics, cardiac glycosides or beta-adrenergic blocking drugs.

Spirometry: Pulmonary functions were measured by the electronic spirometer, model-RMS Helios-702 in accordance with the standards of lung function testing of the American Thoracic Society/European Respiratory Society (ATS/ERS) [16]. The test was explained and demonstrated to the subjects. After a rest for 5–10 minutes, the test was carried out. The best of the three acceptable results was selected. Post bronchodilator (reversibility test) testing was performed 10 minutes after administration of the bronchodilator. Pulmonary function report included patient's gender, height, weight, age and smoking status. Standard spirometric measurements included were forced vital capacity (FVC), forced expiratory volume in one second FEV1, the ratio of forced expiratory volume in one second to forced vital capacity (FEV1/FVC), Forced Expiratory Flow in 25% (FEF25%), Forced Expiratory Flow in 50% (FEF50%), Forced Expiratory Flow in 75% (FEF75%), and Forced Expiratory Flow in 25-75% (FEF25%-75%), peak expiratory flow rate (PEFR). Spirometric parameters were recorded as a percentage of the normal value predicted on reported height and age[17].

Measurement of Anthropometric Parameters: Weight was measured nearest to 0.1 kg using a standardized electronic weighing machine, with the subjects standing without footwear, with light clothes. The height of the subjects was measured with the stadiometer, to the nearest centimetre.

Statistical analysis

The data were expressed in mean ± SD and they were analyzed by SPSS (Statistical Package for Social Sciences) statistical software version 17 using proper statistical test. Differences were considered statistically different when $p < 0.05$

Result:

Out of 3200 test results, 1563 results met inclusion criteria. Among them 35.2% were male subjects and 64.8% were female. The age of subjects ranged between 15-60 years. The mean age of males and females was 35.78 ± 13.7 years and 34.52 ± 11.7 years, respectively. Various anthropometric parameters like, age, weight, height, are shown in Table 1.

Lung volumes (FVC, FEV1) were higher in males and FEV1/FVC ratio were higher in females across all age groups (Table 2)

There is significant negative correlation of spirometric variables (FVC, FEV1, FEV1/FVC ratio) with age (Table-3). These variables significantly ($p<0.05$) decreased with the advancing age in both the genders. Whereas spirometric variables (FVC, FEV1) has significant positive correlation with height (Table-3) in both male and female.

Prediction equations were derived by multiple linear regression for each parameter (FVC, FEV1, FEV1/FVC ratio) based on age and height. Prediction equations, derived separately for males and females of different age groups incorporating age and height as independent variables, are shown in Table-5 and Table-6 respectively.

Discussion:

Lung function varies with ethnicity[18]. A study showed that FVC and FEV1 are significantly lower in Asian-Americans than European-Americans for the same height representing a true physiological difference in the two ethnic groups[18].

It was seen that FVC, FEV1, and FEV1/FVC% have similar values reported by Udwadia et al in West Indians[13] and by Vijayan et al [14] in South Indians , but north Indian population have higher values as reported by Saleem et al[19]. Chhabra et al[20] also observed that vital capacity and other spirometric parameters were higher in adult males of north than of south or west India. Previous studies of ventilatory capacity in South Indians had shown that the subjects had lower values for ventilatory capacities and expiratory flow rate than the subjects from the Western or northern India[11,21]. In our study FVC, FEV1, and FEV1/FVC% have similar values as reported from west[13] and south India[14] but have lower values than the Kashmiri population of north India[19]. These values are also similar to the Chinese[22] and the Pakistanies[23] but are lower than those reported from Western countries[24,25]. It was observed by the authors that people at higher altitudes have significantly higher spirometric values than low-landers in India because of ethnicity, better physique, inherited adaptive response in highlanders and possibly genetic influence[19]. It appears that the physique factor is an indicator of respiratory muscle strength, which is affected by exercise, nutrition, and overall health status[24,25].

Mean spirometric values (FEV1, FVC) were higher in males than in females in both younger and older age groups in our study similar to other reported study from West and South India[13,14]. But FEV1/FVC % is higher in female than in male in our study. These findings are similar to other study reported by previous study[13]. But among the Kashmiri north Indian[19] the FEV1/FVC% is more in male than in female. It is seen that in the present study the spirometric values are less in both male and female when compared with the north Indians[19]. Another study [26] showed that white populations had higher spirometric values than in our population, but the same study also showed that male white population had higher values than white females similar to the observation in the present study. This can be explained as the male has higher mean height, stronger respiratory muscles, greater activity and bigger size of lungs and airways than in female[14]. Airways of women have 17% smaller diameters than the airways of mature men[14]. Boys tend to have larger lungs per unit of stature than girls even though the number of alveoli per unit volume and area was identical; total number of alveoli were more in boys than girls resulting in higher lung function[14].

Previous study showed that there were various predictors for Spirometric variables like age, sex, height, weight[11-14] and BMI[27]. In our study there is a strong positive and significant correlation between spirometric parameters (FVC, FEV1 and FEV1/FVC) and height in both male and female and this finding is similar to the previous studies [9,10,13,24,25].

In our study age is also an important predictor of normal lung function. In healthy Pakistani adults it was observed that age was always found to be important predictors of lung function parameters [23].The present study showed that spirometric values have negative correlation with age in both the sexes and is similar to previous national[14] and international[23, 28, 29] studies. A study [29] observed that spirometric parameters tend to increase with age before 20 years while after 20 years these show a decline. Another study showed that there was no age related decline in FVC in either sex but FEV1 showed an age related decline in men, though not in women[14]. The absence of any age related decline in FVC has also been observed in North Indians[30].

Regression equations for spirometric variables are available from various regions of India. But these studies are two or more decade old. Establishing regression equations to predict spirometric values of normal lung functions on a regional basis in India with diverse conditions is important. In the present study, multiple regression models has been used to obtain equations for normative spirometric values for the eastern Indian population and derived values from these equations were compared with other studies from India.

Prediction equations have been computed for predicting FVC, FEV1, and FEV1/FVC from the age and the height in the studied population. It is remarkable that amongst all the predictors, height is a major part of variability as usual. The body weight in prediction equations showed smaller R^2 change. Thus, in both male and female, for FVC, FEV1 and FEV1/FVC% only height and age were included. Different equations were developed for different age groups. In preliminary analyses, equations derived for the whole age range of the population, showed smaller R2 than were found with linear equations. It is well known that linear regression equations in this setting will result in discontinuities at the junction of the two equations. These norms can be used for practical purpose as the standard errors of estimate (SEE) of the computed equations are sufficiently small. The SEE of the multiple regression equations computed from the present observation were smaller than reported in the earlier studies[13, 14]. This finding indicates that the regression equations computed from the present investigation would predict pulmonary function measurements more precisely and accurately in the population of this part of the country.

A comparative study [31] of Indian reference equations between North, South and West and East showed that these equations do not yield equivalent results in all the regional population.

It was thought that revision of prediction equations can be undertaken in the present scenario with suitable data and recording device. This idea was also supported by the availability of updated technology and measurement protocols. Another thought was that the lung health in East Indian population should change due to changes in various influencing factors in last two decades. Present study indicates towards this idea when compared to the previous studies.

Conclusion:

Normative values and prediction equations for spirometric data was found to be mostly unchanged in the eastern regions of India after two decades. The prediction equations obtained in the present study seems to be superior owing to their substantially smaller standard error of estimate (SEE) than those proposed in the previous study. It highlights the importance of having updated local reference values and normal prediction equations based on normative spirometric data in view of different ethnic background of north, west, south and east regions of India for use in health and disease.

TABLES

Table 1. Baseline characteristics

Characteristics	Genders	Mean ±SD	Minimum	Maximum
Age (years)	Male (n=550)	35.78±13.7	15	60
	Female(n =1013)	34.52±11.7	15	60
Weight (Kg)	Male(n=550)	58.15±11.6	32	99
	Female(n =1013)	53.39±11.6	28	105
Height (cm)	Male(n=550)	163.09±7.9	131	206
	Female(n =1013)	150.98±5.8	132	181

Table 2. spirometric variables as per age and gender

Spirometric variables	AGE (YEARS)	Male No	Mean ±SD	Female No	Mean ±SD
FVC(L)	15-30	234	3.38±0.675	437	2.26±0.46
	31-45	161	3.0±0.58	387	2.01±0.38
	46-60	155	2.54±0.54	189	1.71±0.35
FEV1(L)	15-30	234	2.85±0.58	437	1.95±0.41
	31-45	161	3.38±0.675	387	1.71±0.35
	46-60	155	2.03±0.47	189	1.42±0.323
FEV1/FVC (%)	15-30	234	85.66±7.4	437	86.39±7.3
	31-45	161	82.96±6.9	387	84.9±6.2
	46-60	155	79.6±5.7	189	82.95±7.29

Table-3 :Correlation of spirometric parameters with age

Variables	Gender	Numbers	Pearson correlation coefficient(r)	p-value
FVC	Male	550	-0.460**	0.000
	Female	1013	-0.465**	0.000
FEV1	Male	550	-0.543**	0.000
	Female	1013	-0.489**	0.000
FEV1/FVC	Male	550	-0.396**	0.000
	Female	1013	-0.200**	0.000

**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

Table-4: Correlation of spirometry parameters with height

Variables	Gender	Numbers	Pearson correlation coefficient(r)	p-value
FVC	Male	550	0.640**	0.000
	Female	1013	0.446**	0.000
FEV1	Male	550	0.587**	0.000
	Female	1013	0.430**	0.000
FEV1/FVC	Male	550	0.015	0.727
	Female	1013	0.058	0.063

**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

Table 5. Prediction equations for various spirometric parameters for male subjects

Spirometric variables	Age (Years)	Male	R	R2	SEE
FVC(L)	15-30	(0.052)×height-(0.034)×age-5.37	0.658	0.47	0.49
	31-45	(0.052)×height-(0.076)×age-5.33	0.630	0.40	0.45
	46-60	(0.043)×height-(0.103)×age-4.1	0.651	0.424	0.41
FEV1(L)	15-30	(0.044)×height-(0.027)×age-4.263	0.654	0.43	0.44
	31-45	(0.043)×height-(0.12)×age-4.226	0.600	0.36	0.42
	46-60	(0.032)×height-(0.116)×age-2.76	0.614	0.38	0.35
FEV1/FVC	15-30	-(0.023)×height-(1.78)×age+93.8	0.260	0.015	7.28
	31-45	-(0.025)×height-(1.97)×age+91.83	0.29	0.084	6.7
	46-60	-(0.117)×height-(1.1)×age+101.43	0.265	0.07	5.4

Table 6. Prediction equations for various spirometric parameters for female subjects

Spirometric variables	Age (Years)	Female	R	R2	SEE
FVC(L)	15-30	(0.036)×height-(0.025)×age-3.09	0.468	0.22	0.40
	31-45	(0.025)×height-(0.096)×age-1.48	0.444	0.20	0.34
	46-60	(0.043)×height-(0.103)×age-3.096	0.573	0.328	0.29
FEV1(L)	15-30	(0.032)×height-(0.037)×age-2.753	0.470	0.22	0.23
	31-45	(0.021)×height-(0.09)×age-1.24	0.435	0.19	0.32
	46-60	(0.029)×height-(0.03)×age-2.839	0.542	0.294	0.27
FEV1/FVC	15-30	(0.052)×height-(0.77)×age+80.60	0.260	0.068	7.2
	31-45	-(0.0)×height-(0.85) ×age +87.1	0.133	0.018	6.25
	46-60	(0.105)×height+(0.269)×age+66.6	0.083	0.007	7.4

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