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Study of Pulmonary Function Test to Detect Changes in Pulmonary Function after Treatment For Pulmonary Tuberculosis - a Single Centre Based Study in a Government Run Hospital of West Bengal.

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Abstract : *Treated patients of pulmonary TB have been recognized to be developing chronic obstructive pulmonary diseases. Treated pulmonary TB patients are free from Mycobacterium infection but have variable presentation of lung function findings affecting the quality of patient's life. The histopathological abnormalities after treatment for pulmonary TB include fibrosis, bronchiectasis, and bronchial stenosis, all of which can cause pulmonary function abnormalities.So a study was framed with an aim to measure the extent of the impairment of lung function in pulmonary TB-treated patients in India, so that proper planning to ensure the functional restoration in lungs in treated patients can be done. 242 patients with pulmonary function test results were analyzed twice, once just after completion of drug therapy and next after 6month of 1st study. Results were tabulated and it was found that there was significant difference between Post treatment and 6month post treatment values of FVC and significant difference between Post treatment and 6month post treatment values of FEV1/FVC. So it can be concluded that disease affects the functional capability and has its own patho physiological manifestation. This phenomenon indicates the possibility that healing and recovery of the lungs are still going on even after stopping all anti-TB therapy as per the recommendation of the regimen. Pulmonary function test(PFT) ,at regular interval even after completion of anti tubercular treatment is a very useful indicator of change of functional capability of lungs.*

Key words: *Pulmonary Tuberculosis, PFT.*

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I. Introduction

Despite microbiological cure observed in the majority of pulmonary TB patients, some of them experience functional lung sequelae and pulmonary impairment which have been shown to contribute to TB burden [1,2] .The histological and anatomic changes during pulmonary TB include bronchial distortion, bronchiectasis, emphysematous changes, and fibrosis [3].

Pulmonary tuberculosis (TB) can cause parenchymal destruction by up-regulation of several proteases and dysregulation of protease control.[4] The histopathological abnormalities after treatment for pulmonary TB include fibrosis, bronchiectasis, and bronchial stenosis, all of which can cause pulmonary function abnormalities.[5,6]. Previous studies have evaluated the changes in pulmonary function before, during and after pulmonary TB treatment.[7,8] Between 48.7% and 76% of patients had pulmonary function abnormalities after completing

pulmonary TB treatment.[9,10,11,12,13,] Although some studies have shown obstructive defects as the main abnormality, recent studies have shown that abnormalities could be obstructive, restrictive, or mixed defects.[14,15].Pulmonary TB has its function sequelae also on asymptomatic-treated patients with its impairments.[16,17] The clinical manifestation appears due to pulmonary dysfunction with functional changes in the lung tissue by hyperinflation and restriction of the lungs and rise or decline of their elasticity.[18]Treated patients of pulmonary TB have been recognized to be developing chronic obstructive pulmonary diseases. Treated pulmonary TB patients are free from *mycobacterium* infection but have variable presentation of lung function findings affecting the quality of patient's life.[18,19-21]

The results of several studies which evaluated the pulmonary function after pulmonary TB treatment show that more than half of patients who completed pulmonary TB treatment have lung function impairment.

These ventilatory changes are either obstructive, restrictive or mixed with different grades of severity of the lung function impairment[22]

In a study performed on gold miners in South Africa, forced expiratory volume in the first second (FEV1) and forced vital capacity (FVC) were found to be worse six months after tuberculosis treatment and were stabilized 13 to 18 months after treatment.[23]The impairment in pulmonary function after completing pulmonary TB treatment is related to long-term respiratory symptoms, which affect quality of life.[24,25]
With this background scientific knowledge, the present study was performed.

The aim of the study is the need to measure the extent of the impairment of lung function in pulmonary TB-treated patients in India, so that proper planning to ensure the functional restoration in lungs in treated patients can be done. Hence, this study aims to evaluate the pulmonary function status at different intervals in patients after been treated for pulmonary TB.In addition, little is known about the relationship between symptoms of tuberculosis, initial radiological changes due to pulmonary TB and decrease in lung function of patients who have completed treatment of tuberculosis. Therefore, this study was also conducted to describe ventilation changes and its associated factors among patients successfully treated for pulmonary tuberculosis.

II. Materials and Methods

The inclusion criteria for the selection of patients in this study were as follows: 1) typical fibro cavitary pulmonary infiltrates on standard chest radiographs; 2) at least one smear positive sputum for Mycobacterium tuberculosis.

The exclusion criteria for the patients in this study were as follows: 1) detection of mono- or multidrug-resistant TB bacilli in the first positive sputum culture; 2) coexisting lung disease, defined as reliable confirmation of lung pathology other than TB; and 3) patients with chronic heart, liver, and kidney failures, metabolic disorders, and pregnancy.

Patients from January 2018 to December 2018, (1,576) patients with culture-confirmed pulmonary TB were identified at the kolkata based Government medical college, of Eastern India. Among these patients, 340 (21.5%) underwent pulmonary function tests after completing pulmonary TB treatment. Ninety-eight patients were excluded from further analysis due to the presence of the following conditions: (1) pulmonary co-morbidities, including asthma, chronic obstructive airway disease (COPD) confirmed by spirometry, pneumoconiosis, interstitial lung disease, history of respiratory failure requiring mechanical ventilation, lung cancer, and lung resection; (2)congestive heart failure (New York Heart Association functional class 2); (3) autoimmune disease; and (4) human immunodeficiency virus infection [26]

The remaining 242 patients with pulmonary function test results were analyzed twice, once just after completion of Drug therapy and next after 6month of 1st study.

Daily calibration was performed for each PFT machine before measuring pulmonary function. Patient data, including age, sex, weight, height, medication history, and smoking status, were collected via standard questionnaires prior to pulmonary function testing. Pulmonary function tests were performed by attending doctor with the patients in sitting postures. Each patient performed at least three acceptable forced expiratory manoeuvres, which fulfilled the criteria of repeatability[27]

The reference equations for FEV1, FVC, and FEV1/FVC were obtained from a few previous studies and were used to calculate the predicted values of corresponding pulmonary function parameters.[28]

Normal pulmonary function should have FEV1 ≥80%, FVC ≥80%, and FEV1/FVC ≥70% ofpredicted values.

For abnormal pulmonary function, an obstructive defect was defined as FEV1/FVC<70%, a restrictive defect as an FEV1/FVC ratio ≥70% and FVC <80%, and a mixed defect as FEV1/FVC <70% and FVC <80% of predicted values.P1

III. Results

Observation of our study is tabulated as follows:

Table 1: Baseline characteristics of the participants

Age(yrs) Mean±SD	Weight(Kg) Mean±SD	Sex(n/%)	Marital status	Education	Occupation
45.2±21.32	58.24±18.45	Female92(38.01%)	Unmarried 51(21.07%)	Primary 76(31.4%)	Domestic work 80(33.05%)
		Male150(61.98%)	Married 165(68.18%)	Secondary 112(46.28%)	Agriculture 60(24.79%)
		Total 242(100%)	Separated/Widowed 26(10.74%)	Higher 54(22.31%)	Factory worker 102(42.14%)

Table 2 : Clinical signs among the observed patients(n/%)

Dyspnoea	Cough	Expectoration	Hemoptysis	Fever	Night Sweat
174(72%)	242(100%)	192(80%)	72(30.2%)	70(29.1%)	133(55%)

Table 3 : Interpretation of PFT

Type of Pathology	No. of cases(n)	Percentage(%)
Obstructive	101	42.01%
Restrictive	26	11.02%
Mixed	115	47.5%

PFT findings of 242 patients were also tabulated in excel sheet for statistical study.

Statistical analysis:

Table A:

t-Test: Paired Two Sample for Means	**FVC(Post treatment)L**	**FVC(6 month post)L**
	Variable 1	***Variable 2***
Mean	**1.649297521**	**1.603471074**
Variance	**0.426363405**	**0.439107404**
Observations	**242**	**242**
Pearson Correlation	**0.946400587**	
Hypothesized Mean Difference	**0**	
df	**241**	
t Stat	**3.306757472**	
P(T<=t) one-tail	**0.000543919**	
t Critical one-tail	**1.651200843**	
P(T<=t) two-tail	**0.001087837**	
t Critical two-tail	**1.969856158**	

Statistical calculations showing significant difference between Post treatment and 6month post treatment values of FVC.

Table B:

t-Test: Paired Two Sample for Means	**FEV1/FVC(Post treatment)**	**FEV1/FVC(6 month post treatment)**
	Variable 1	***Variable 2***
Mean	**64.21764463**	**63.99979339**
Variance	**288.9253359**	**248.4598029**
Observations	**242**	**242**
Pearson Correlation	**0.700575583**	
Hypothesized Mean Difference	**0**	
df	**241**	
t Stat	**0.266283086**	
P(T<=t) one-tail	**0.395124439**	
t Critical one-tail	**1.651200843**	
P(T<=t) two-tail	**0.790248877**	
t Critical two-tail	**1.969856158**	

Statistical calculations showing significant difference between Post treatment and 6month post treatment values of FEV1/FVC.

IV. Discussion

In our present study it is obvious that, mean age of the 242 patient examined in this study is 45.2±21.3 years.

Mean body weight of the same study group is 58.24±18.45 kilogram.

Out of 242 total cases(n=242),38.01% are female(n=92) and 61.98% are male(n=150).

As we studied the socioeconomic status of the study group,68.18% cases came out to be married(n=165).

21.07% cases came out to be unmarried(n=51).

Regarding education status, majority of the patient(n=112,46.28%) are educated upto secondary school level and (n=76,31.4%) cases are educated upto primary school level.

Regarding occupation,33.05% cases are engaged in domestic work(n=80),24,79% and 42.14% cases are engaged as agricultural and factory worker respectively.(table 1)

Table 2 elaborates the clinical presentation of the patients. Cough was a presentation in 100% cases and 72% cases presented with dyspnoea of variable degree.30% cases presented with hemoptysis and in 80% cases, there was expectoration. Fever and night sweat were the presenting features in 29% and 55% cases.(Table 2)

While interpreting PFT reports, Obstructive pathology was more prominent in 42.01% cases. Mixed type of lesion was present in 47.5% cases[26]. 11.02% cases came out to be of restrictive pulmonary pathology pattern.(Table 3)

The tabulated data was statistically analyzed and Table A showed Statistical calculations showing significant difference between Post treatment and 6month post treatment values of FVC.

Similarly Table B showed Statistical calculations showing significant difference between Post treatment and 6month post treatment values of FEV1/FVC.

Co-morbidities could affect pulmonary function test results, including chronic lung diseases, severe congestive heart failure, autoimmune diseases, and HIV infection. Autoimmune diseases could have pulmonary involvement, possibly leading to significant changes in pulmonary function.[29]In addition, patients with HIV infection have a high risk of contracting respiratory diseases such as Pneumocystis carini infection and recurrent bacterial pneumonia.[30] Therefore, in our study, we excluded patients with these co-morbidities to give a more accurate description of the changes in pulmonary function and trends after completion of pulmonary TB treatment.The time course for changes in pulmonary function after completing anti-tuberculosis treatment has never been well studied. One previous study showed that the annual decrease in FEV1 was 35.3 mL in patients with obstructive defects within 15 years after the end of anti-tuberculosis treatment.[31] However, the anti-tuberculosis treatment in this study was less effective than the modern four-drug combination regimen, and exposure to other noxious environmental factors may have contributed to changes in pulmonary function during long follow-up time periods.However in our study we had only the opportunity to record the PFT twice in our patients, once just at the end of treatment and last was after a 6 month interval after the treatment was complete.

Similar to our finding,in one study we saw, the pulmonary impairment was present in 45.6% of patients including airway obstruction, restrictive pattern in 9.2% of patients, and 43.1% of patients had combined pattern.[32]Abnormal PFT findings were 5.4 times more likely in survivors of pulmonary TB patients.[33] Verma et al., in his study, found 16.3% of patients had obstructive airway disease and mixed obstructive with restrictive disorder was found in 22.8% patients.[33] Our study had much lower impairment findings as compared to other studies due to selection criteria of uncomplicated patients. Furthermore, variable pulmonary function impairment was noted by authors in their study on patients treated with short-course TB regimen.[33]

Obstructive and combined obstructive and restrictive lung function patterns were the predominant abnormalities while some found restrictive abnormality to be more common.[34]In only one anti-TB treatment group, 20% of patients had no changes in lung function and 53.3% had mild disorder.[35] Similar to our findings, a study had also noted that 9.7% of participants as having mild impairment, but it also had 16.5% of participants with moderate impairment, and 9.7% of having severe lung impairment not matching to our findings. Furthermore, 56% of the cases were found to have moderate to advanced residual damage to the lungs by Mohamad Saleh.[35]

Although the extensive destruction of lung parenchyma in PTB with consequent restriction of airflow through the bronchial tree is clinically relatively common, the severity of airflow obstruction(AFO) and bronchodilator response have still not been evaluated objectively.[36,37] Most of all symptoms and limitations, including AFO, of these patients in everyday practice consider as a consequence of active or cured pulmonary TB and in most cases ignored the emergence of severe clinical manifestations and complications. All the mechanisms of systemic inflammatory response in the pathogenesis of AFO in active PTB remained still unclear, but it is certain that some inflammatory conditions act as exclusively linked.According to the current GOLD criteria, there is increasing awareness of the heterogeneity of COPD. These criteria require the presence of chronic airflow limitation (CAO) that persists after use of a bronchodilator and a history of exposure to recognized risk factors for the development of AFO. Among these risks, the most common are cigarette smoking, biomass fuel dust exposure, childhood lung infections, and occupational exposures, including exposure to dust, gases, and fumes.[38,39] The absence of tobacco-smoking history occurs in .20% of patients fulfilling the criteria for COPD by spirometry and has been reported in many population-based studies.[40,41]Whether TB should be added to the list of recognized exposures for the future development of COPD is unclear at this point of time.A number of studies have shown that the treatment of pulmonary TB only with antituberculosis drugs may lead to the emergence or worsening of existing AFO in some patients. Some prospective studies with a longer follow-up period demonstrated a significant number of cases affected and/or treated for PTB, which had the same result in CAO, or the restrictive respiratory syndrome.[42]

V. Conclusion

Adequate and timely treatment of TB has reduced the burden of the disease but values for PFT were significantly lower in patients who had been treated for pulmonary TB. For TB treatment completed patients, there is microbiological cure but the study indicates the presence of pulmonary functional limitations in patients. Thus, disease affects the functional capability and has its own patho physiological manifestation. This phenomenon indicates the possibility that healing and recovery of the lungs are still going on even after stopping all anti-TB therapy as per the recommendation of the regimen.

Pulmonary function test(PFT) ,at regular interval even after completion of anti tubercular treatment is a very useful indicator of change of functional capability of lungs.

Limitations of the study: There are some limitations of our study. First, the study was limited by a small sample size. Without longitudinal follow-up data, we could miss individual characteristics that might have significant impacts on pulmonary function.

Secondly, selection bias might exist because our study population was treated in a government run medical college in a metro city. Nevertheless, we believe that this is a minor concern because more than 90% of the patients with pulmonary TB were ambulatory and sought primary care in the outpatient department.

Third, only **21.5%** of our patients underwent pulmonary function tests after completing antituberculosis treatment. Patients who received pulmonary function tests could have had more prominent respiratory symptoms and worse pulmonary function compared to patients who did not undergo such tests.

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