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Clinical and Pulmonary Function Evaluation in Post-Pulmonary Tuberculosis Patients

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Abstract

Introduction: Globally, the best estimate is that 10.0 million people (range, 9.0 - 11.1 million) developed TB disease in 2017. TB is an infectious disease caused by the bacillus Mycobacterium tuberculosis which typically affects the lungs. But many of the fully treated post-tubercular patients are left with permanent changes in lung anatomy (bronchial and parenchymal structural) and are at higher-risk of pulmonary sequelae and premature mortality. They affect the calibre of airways, increase their resistance and decrease airflow. Aim of our study was to determine overall clinical status and pulmonary function through spirometry of the cured post-pulmonary TB patients.

Material and methods: Study was conducted on patients above 18 years of age, coming to the OPD of Pulmonary Neducue department at Santosh Medical College, Ghaziabad, and taken complete treatment under RNTCP in past and declared cured. At the time of study, 200 patients with sputum smear negative for AFB were enrolled in the study. The study was conducted for 9 months after seeking clearance from the Institutional Ethical Committee. Written informed consent was taken from all the patients included in the study. Detailed socio-demographic history, clinical history especially regarding pulmonary symptomatology, details of past anti-tubercular treatment were recorded as per proforma. General physical and detailed chest examination was carried-out. All these patients were subjected to chest X-ray examination, sputum microscopy, and pulmonary function study. Result: Mean age was 51.72 ± 11.89 years (mean ± SD). Mean BMI was 19.23 ± 2.95 Kg/m2 (mean ± SD). Males were 77% and females were 23%. Illiteracy was seen in 34% while only 6.5% were graduate. In present study 84% of participants had dyspnoea and 63.5% had cough. Haemoptysis was seen in 11.5%.Post-tuberculosis 94% patients had fibrosis on their chest X-ray followed by pleural thickening and pleural calcification 28.5%, healed lesions in 24%, destroyed lung 22%, fibro-cavitary lesions in 17.5% , bronchiectasis in 13.5% and only 2% showed normal chest radiograph. In present study we observed that 47.5% patients had mixed blockage in their spirometry post-tuberculosis followed by restrictive finding in 30% of the patients and obstructive in 13.5% of the patients, and only 9% patients had normal spirometric results. Our study also classified both restrictive and obstructive pattern. It showed 2% mild, 11% moderate and 17% severe type of restrictive pattern. It was also found that mild and moderate obstruction was 2% each whereas 5% had severe and 4.5% had very severe obstruction.

Conclusion: In the absence of proper guidelines, most of the post-tubercular lung function impairment patients either suffer in silence or continue to receive irrelevant treatment. Therefore proper guidelines must be made regarding follow-up of patients post-tuberculosis treatment, to assess their lung functions and provide correct management so as to improve their quality of life.

Key words: Tuberculosis; pulmonary function; post-tubercular symptoms; pulmonary sequelae; pulmonary function impairment; spirometry; variable patterns and severity of lung impairment.

Introduction

Tuberculosis, caused by *Mycobacterium tuberculosis*, is a major cause of death worldwide, being the most communicable disease in the world, affecting one-third population. It is estimated that 2 out of every 5 people are infected with TB in India. In 2017, TB caused an estimated 1.3 million deaths (range, 1.2 - 1.4 million) among HIV-negative people and there were an additional 3,00,000 deaths from TB (range, 2,66,000 - 3,35,000) among HIV-positive people[1]. Globally, the best estimate is that 10.0 million people (range, 9.0 - 11.1 million) developed TB disease in 2017.

Considering the enormous burden of disease and limited resources, presently the focus is on early detection and full treatment of affected patients. But many of the fully treated post-tubercular patients are left with permanent changes in lung anatomy and are at higher-risk of pulmonary sequelae and premature mortality[2-5]. These result in pulmonary sequelae that are characterised by bronchial and parenchymal structural changes, including bronchovascular distortion, bronchiectasis, emphysematous changes, and fibrotic bands. Moreover, these changes remain permanently in the lungs after a microbiological cure[6]. They affect the calibre of airways,

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increase their resistance, and decrease airflow. The mechanism of fibrotic scarring can also result in reduced total lung capacity[7]. Therefore delay in diagnosing TB has been shown to relate directly to the severity of pulmonary damage and the frequency of residual morbidities negatively affecting the quality of life and leading to pulmonary disability[8]. Inadequate treatment of bronchial obstruction in patients with active TB can ultimately lead to chronic airway obstruction syndrome, with clinical manifestations very similar to chronic obstructive pulmonary disease. The major burden of both chronic obstructive pulmonary disease (COPD) and pulmonary tuberculosis (PTB) occurs in low and middle income countries. Ninety per cent of the estimated of 3 million death from COPD, and a large majority of the 9 million cases of active PTB occur in these countries[9]. In these populations, factors other than cigarette smoking, (e.g., biomass fuel, and occupational exposure) contribute to the pathogenesis of COPD[10]. In a number of large population-based cross-sectional studies, PTB has also been shown to be strongly associated with the presence of chronic airflow limitation (CAL)[11-14]. In some studies, this association is almost as strong as that for cigarette smoking[13-15].

A total of seven TB guidelines have addressed patient follow-up after TB treatment, but only three have mentioned the problem regarding TB sequelae, while four others have stated about the risk of relapse or recurrence of tuberculosis[16-18]. In an international guideline, it was indicated that early diagnosis of TB may lead to fewer post-tuberculosis sequelae[19]. Two other guidelines explained about the problem of long-term TB sequalae, but both were written for low-burden TB countries. One of the guidelines emphasized on the need of post-TB management and support to address TB sequelae and the other indicated no need for clinical monitoring after TB cure[20,21]. None of these guidelines mentioned about how potential TB sequalae should be identified or managed. Hence, we focussed to determine overall clinical status and pulmonary function through spirometry of the cured post-pulmonary TB patients.

Aims and objectives

1. To determine the pulmonary and overall clinical status of the cured pulmonary TB patients.
2. To determine pulmonary function of these patients through spirometry.

Material and methods

Type of study: Cross-sectional study.

Place of study: Department of Pulmonary Medicine, Santosh Medical College and Hospital, Ghaziabad, Uttar Pradesh. Institutional Ethics Committee clearance was taken before commencing the study. Written informed consent was taken from all the patients included in the study.

Duration of study: 9 months

Study sample: Study population comprised of following patients.

1. Those who completed treatment and declared cured under RNTCP guidelines in Santosh Medical College, Ghaziabad in last five years.
2. Patients coming to the OPD of Pulmonary Medicine department, Santosh Medical College, Ghaziabad and taken complete treatment under RNTCP in the past five years. 200 patients were enrolled in the study.

***Inclusion criteria*:** 1) Age 18 to 65 years; 2) sputum smear for AFB negative at the time of study.

Exclusion criteria: Smear positive for AFB. 2) Any other respiratory disease other than a sequelae of TB. 3) Cardiac co-morbidities of any type. 4) Not willing to participate and give informed written consent. 5) Patients who are unable to perform spirometry. 6) H/o DM, HTN, Hypothyroid, chest wall abnormalities, seizures, etc.

Detailed socio-demographic history, clinical history (especially regarding pulmonary symptomatology), details of past anti-tubercular treatment were recorded as per the proforma. General physical and detailed chest examination was carried-out. All these patients were subjected to chest X-ray examination, sputum microscopy, and pulmonary function study.

Pulmonary Function Test: The pulmonary function tests were conducted according to ATS/ERS guidelines using Portable spirometer of RMS. The entire FVC procedure was demonstrated satisfactorily to the subjects. Nose clips were attached before the test. The subjects were asked to take maximal inspiration and blow into the mouthpiece as rapidly, forcefully, and completely as possible for about 6 seconds. The subjects were verbally encouraged to continue to exhale the air at the end of manoeuvre to obtain optimal effort. A minimum of 3 acceptable Forced vital capacity (FVC) manoeuvres were performed in the standing position with nose pinched and the best manoeuvre were selected and accepted. The parameters measured were Forced Vital Capacity (FVC), Forced Expiratory Volume in 1 second (FEV1), FEV1/FVC ratio, Peak Expiratory Flow rate (PEFR) and Forced Expiratory Flow rate (FEF 25-75).

Statistical analysis

The data were entered on a Microsoft Excel spreadsheet

and imported into Statistical Package for Social Sciences (SPSS) version 22 for statistical analysis. Frequency distribution tables were produced, and the Fishers exact test was used to assess associations of variables. A P value less than 0.05 was considered statistically significant.

Results

Mean age was 51.72 ± 11.89 years (mean ± SD). Mean BMI was 19.23 ± 2.95 Kg/m^2 (mean ± SD). Males were 77% and females were 23%. Illiteracy was seen in 34% while only 6.5% were graduate (Table I). Mean duration since completion of ATT at the time of follow-up study was 19.21 ± 1.34 months (mean ± SD).

Table I: Socio-demographic profile of the participants.

Mean age in years (mean ± SD)	51.72 ± 11.89
Mean BMI in Kg/m^2 (mean ± SD)	19.23 ± 2.95
Gender	No. (%)
Male	154 (77)
Female	46 (23)
Education level	No. (%)
Illiterate	68 (34)
Upto 5th std	38 (19)
6th - 8th	36 (18)
High school	31 (15.5)
Intermediate	14 (7)
Graduate	13 (6.5)
Marital status	No. (%)
Married	182 (91)
Unmarried	14 (7)
Widower	4 (2)

In the present study, 84% of participants had dyspnoea and 63.5% had cough. Haemoptysis was seen in 11.5% (Table II).

Table II: Symptoms of participants.

Symptoms	Present No. N-200 (%)	Absent No. (%)
Cough	127 (63.5)	73 (36.5)
Dyspnoea	168 (84)	32 (16)
Chest Pain	114 (57)	86 (43)
Fever	59 (29.5)	141 (70.5)
Haemoptysis	23 (11.5)	177 (88.5)

Post-tuberculosis, 94% patients had fibrosis on their chest X-ray followed by pleural thickening and pleural calcification each 28.5%, healed lesions in 24%, destroyed lung 22%, fibro-cavitary lesions in 17.5%, and bronchiectasis in 13.5%. Only 2% showed a normal chest radiograph (Table III).

Table III: Chest X-ray findings.

Chest X-ray findings	(n 200)	%
Destroyed lung	44	22
Fibro-cavitary lesions	35	17.5
Bronchiectasis	27	13.5
Fibrosis	188	94
Healed lesions	48	24
Pleural calcification	57	28.5
Pleural thickening	57	28.5
Normal	4	2

Pulmonary function study showed that 47.5% patients had mixed blockage followed by restrictive finding in 30% of the patients and obstructive pattern in 13.5% of the patients. Only 9% patients had normal spirometric results (Table IV).

Table IV: Post-tubercular treatment spirometric findings.

Findings (patterns)	No.	%
Normal	18	9
Obstructive	27	13.5
Restrictive	60	30
Mixed Blockage	95	47.5
Total	200	100

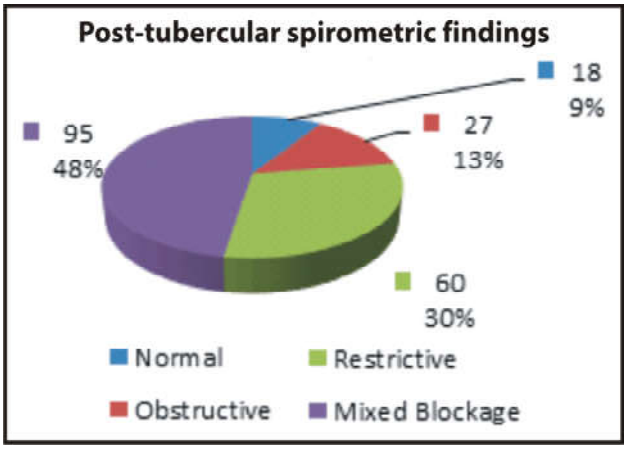

Fig. 1:

We also further classified both restrictive and obstructive pattern on the basis of severity. It showed 2% mild, 11% moderate, and 17% severe type of restrictive pattern. It was also found that mild and moderate obstruction was 2% each, whereas 5% had severe, and 4.5% had very severe obstruction (Table V).

Table 2- Symptoms of participants

Table V: Patterns of spirometry (severity).

Pattern	No.	%
Normal	18	9
Mild Restriction	4	2
Moderate Restriction	22	11
Severe Restriction	34	17
Mild Obstruction	4	2
Moderate Obstruction	4	2
Severe Obstruction	10	5
Very Severe Obstruction	9	4.5
Mixed Blockage	95	47.5
Total	200	100

Table VI: Comparative analysis on the basis of number of times of ATT intake.

		Past H/o ATT once (N - 129)	Past H/o ATT twice (N-71)	Fishers exact test value	P value significant (<.05)
Cough	yes	102	66	.0144	Yes
	no	27	5		
Dyspnoea	yes	105	63	.2273	No
	no	24	8		
Chest X-ray Findings	yes	125	71	.2992	No
	no	4	0		
Abnormal PFT	yes	111	71	.0004	Yes
	no	18	0		

Discussion

Demographic profile

In our study, maximum number of patients were in the age group of 41 - 60 yrs (57%) followed by 22.5% in age group 21 - 40 yrs. Only 20.5% of patients were above 60 yrs of age. Mean age of patients was 51.72 ± 11.89 years (mean ± SD) as compared to Pandey *et al*[22] where mean age was 42.84 ± 16.5 years (mean ± SD). The mean BMI was found to be 19.23 ± 2.95. The finding of the present study correlates with a study conducted by Pandey *et al*[22] with BMI of 20.24 ± 4.44. Illiteracy was seen in 34% while only 6.5% were graduate. Literacy is one of the important factors which can help the patients to understand the disease process and its outcome. It can also help them to recognise their symptoms and seek consultation for their symptoms as early as possible.

Post-tubercular treatment symptoms

In the present study, 84% of participants had dyspnoea and 63.5% had cough. Haemoptysis was seen in 11.5%. A study conducted by Patil *et al*[23] showed that among 500 symptomatic subjects who were included in the study, the most common post-tubercular symptom was of breathlessness in 79% cases, followed by cough in 48%. In a study conducted by Pandey *et al*[22], post-tubercular symptom was of breathlessness in 96% of the patients followed by cough in 58%, sputum production in 18%, and haemoptysis in 9% of the patients.

Radiological changes after tuberculosis

Post-tuberculosis, 94% patients had fibrosis on their chest X-ray followed by pleural thickening and pleural calcification in 28.5%, healed lesions in 24%, destroyed lung 22%, fibro-cavitary lesions in 17.5% , bronchiectasis in 13.5% and only 2% showed normal chest radiograph. One systematic review assessed pulmonary abnormalities with radiological imaging among people with a history of TB and found proportions of between 8.3% - 83.7% for cavitation, 4.3% - 11.2% for bronchiectasis and 25.0% - 70.4% for fibrosis[24].

Post-tuberculosis respiratory function impairment

Normal pulmonary function test: as post-bronchodilator FEV1/FVC >=95%, FVC > 80% of normal predicted value.

Defining restrictive pattern: Patient with restrictive stage COPD as post-bronchodilator FEV1/FVC >=70% , FEV1 < 80% of normal predicted value, FVC< 80% of normal predicted value.

Severity

Mild restriction: FEV1/FVC > 95%, FVC< 80% of normal predicted value.

Moderate restriction: FEV1/FVC > 95%, FVC< 64% of normal predicted value.

Severe restriction: FEV1/FVC > 95%, FVC < 44% of normal predicted value.

Defining obstructive pattern: Patient with obstructive stage COPD as post-bronchodilator (FEV1/FVC) < 70% and FEV1 < 80%, FVC > 80% of normal predicted value.

Severity

Mild stage COPD: (FEV1/FVC) pred% < 70 or < 95% and FEV1 >= 80% of normal predicted value.

Moderate stage COPD: (FEV1/FVC) pred% < 70 or < 84% and FEV1 >=50 and < 80 of normal predicted value.

Severe stage COPD: (FEV1/FVC) < 70% and FEV1 >=30% and < 50% of normal predicted value.

Very severe stage COPD: (FEV1/FVC) pred% < 70 and FEV1 >=0 and < 30 of normal predicted value.

Defining mixed pattern: Patient with mixed blockage as post-bronchodilator (FEV1/FVC) Pred < 95 % and FVC % Pred < 80.

The above data signifies that pulmonary tuberculosis can lead to significant damage of the lung parenchyma thereby leading to various functional abnormalities.

In the present study, we observed that 91% (182/200) patients had pulmonary function abnormality on spirometry. Other studies have described lung function abnormality ranging from 46% to 82%[22,26,28]. Mixed blockage was the most prevalent functional abnormality on spirometry in our study, seen in 47.5% (95/200) of patients, followed by restrictive findings in 30% (60/200)of the patients and obstructive in 13.5% (27/200) of the patients.

Many studies have described pulmonary restriction as the predominant pattern with various proportions[25,26,27]. This restrictive pattern has been explained by the destruction of lung parenchyma volume loss, lung scarring with a reduction of pulmonary compliance and an increase in elastic retraction pressure[29]. On the contrary, some other studies showed that airflow obstruction was the most common defect[12]. The pathophysiology of airflow obstruction following pulmonary tuberculosis treatment is not clear. Bronchial stenosis has been speculated as the result of extrinsic pressure of enlarged peribronchial lymph nodes as well as the consequence of endobronchial involvement of TB with extensive granulation tissue destruction and subsequent fibrosis[30]. Moreover, similar to exposure to smoke, TB increases the activity of metalloproteinases enzymes, contributing to pulmonary damage[31]. Gothi *et al* also demonstrated that post-tuberculous airflow obstruction could be the consequence of obliterative bronchiolitis[32]. Our study also classified severity of both restrictive and obstructive pattern. It showed 2% mild, 11% moderate, and 17% severe type of restrictive pattern. It was also found that mild and moderate obstruction was 2% each, whereas 5% had severe and 4.5% had very severe obstruction. Only few studies have classified such detail. In a study conducted by Manji *et al*[28], the overall prevalence of lung function abnormalities was 74% (371/501) where majority was due to obstruction (42%) (210/501) followed by mixed (19%) (96/501) and restrictive (13%) (65/501) abnormalities. In their study, approximately 79% (166/210) of patients with obstructive dysfunction had mild-to-moderate severity while 73% (47/65) of patients with restrictive abnormalities had mild-to-moderate severity. In our study, only 30% of obstructive patients had mild-to-moderate severity, and 70% of them had severe obstruction. Also, 43% of restrictive patients had mild-to-moderate severity and 57% had severe form of restrictive pulmonary impairement. In other words, severe form of both obstructive and restrictive pattern were more prevalent as compared to other studies. Another study by Pasipanodya *et al* (2007) in the USA, the prevalence of abnormal lung function of any type was 59%, and the prevalence of individual subtypes of impairment for restrictive, obstructive and mixed were 31, 15 and 13% respectively[33], where majority was with restrictive pattern. While the prevalence of pulmonary impairment was as high as 91% (182/200) in our study, it suffices to note that pulmonary functions are abnormal in the majority of patients upon completion of chemotherapy. Mixed blockage 47.5% (95/200) was most prevalent in our study.

In our study, analysis on the basis of number of times of ATT intake revealed that patients who took ATT twice were significantly more likely to have cough (p = .0144) and abnormal PFT findings (p = .0004) as compared to those who took ATT only once. In the Manji *et al*[28] study, patients with recurrent TB were also more likely to have abnormal lung functions compared to those with a first episode of TB (89.3% vs 71.4%) (p = 0.001). As there were only 4 patients in our study (all with history of ATT intake once only) who did not have any radiological findings, understandably there was no statistically significant difference between two groups based on number of times of ATT intake (Table VI). Further, it can be said that despite almost all the patients having abnormal chest X-ray findings, many of these were asymptomatic[32] and had a normal pulmonary function study[18].

These non-communicable post-tuberculous sequelae bring to light the often overlooked processes by which TB impacts the quality of life. Tuberculosis therefore imposes an infectious and non-infectious burden on the healthcare infrastructure. While the infectious and microbiologic domain has received much attention in TB treatment, a lot is still left to be desired in the non-infectious sequelae. International TB guidelines do not address the importance of lung function impairment after tuberculosis, particularly omitting guidance on identification and management. This is concerning because of global rise in mortality and morbidity from non-communicable diseases, including post-tubercular sequelae[34,35]. Consequently, the national TB control programmes are not designed to adequately deal with the problem of post-tubercular lung function impairment.

In view of high TB burden and comparatively limited resources, the national programme in our country is focused on early diagnosis and treatment of active disease only. Due to this, bacteriological confirmation of cure at the end of the treatment is usually the end-point in TB patient care. Therefore there is a need for creating awareness regarding post-tuberculosis sequelae and lung function impairment among policy makers, practitioners, and patients. At least the healthcare staff should be made aware of the increased risk of symptoms due to post-tubercular lung function

impairment, so that they can educate about and discuss the health implications of residual lung damage with patients and their relatives. Unfortunately, post-TB lung function assessment services are often not yet established.

Conclusion

The magnitude of residual lung function abnormalities among patients with tuberculosis is high despite successful administration of anti TB medications. Studies that look at the quality of life and socio-economic impact of residual lung function abnormalities, screening strategies and treatment need to be conducted to supplement the findings of this study. As there are no proper guidelines regarding follow-up of patients with post-tubercular lung function impairment, most of the patients either suffer in silence or continue to receive irrelevant treatment. Therefore proper guidelines must be made regarding follow-up of patients post-tuberculosis treatment, to assess their lung functions and provide correct management so as to improve their quality of life.

Limitations

1. Smokers were not excluded from our study. 46 patients were smokers but never had other respiratory diseases in past, hence were enrolled in our study.
2. We could not follow-up asymptomatic patients as they did not turn up in our OPD. Only few studies have compared post-tubercular symptomatic and asymptomatic patients.

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