THE EFFECT OF APPROPRIATE ANTI TUBERCULOUS TREATMENT ON RECOVERY OF PULMONARY AND PLEURAL TUBERCULOSIS AND THE IMPACT OF TUBERCULOSIS ON LUNG FUNCTION AND QUALITY OF LIFE IN NEWLY DIAGNOSED PATIENTS

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF M.D. PULMONARY MEDICINE EXAMINATION OF THE TAMIL NADU DR. M.G.R. UNIVERSITY, CHENNAI TO BE HELD IN MAY, 2020

CERTIFICATE

This is to certify that the dissertation "The effect of appropriate Anti tuberculous treatment on recovery of pulmonary and pleural tuberculosis and the impact of tuberculosis on lung function and quality of life in newly diagnosed patients" is a bonafide work of Dr. Dhivya Roy carried out under our guidance towards the M.D. Pulmonary Medicine Examination of the Tamil Nadu Dr. M.G.R. University, Chennai to be held in May, 2020.

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DECLARATION

This is to certify that the dissertation titled "The effect of appropriate Anti Tuberculous Treatment on recovery of pulmonary and pleural tuberculosis and the impact of tuberculosis on lung function and quality of life in newly diagnosed patients" which is submitted by me in partial fulfilment towards M.D. Pulmonary Medicine Examination of the Tamil Nadu Dr.M.G.R. University, Chennai to be held in May 2020, comprises my original research work and information taken from secondary sources has been given due acknowledgement and citation.

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ABSTRACT

BACKGROUND AND AIM:

Lung function impairment after pulmonary tuberculosis (PTB) is a recognized phenomenon which adds to morbidity in these patients. However how the lung function changes over the course of illness is not studied. So our study aimed at assessing the change in lung function from the time of diagnosis through the course of illness to treatment completion and also to identify the individuals with lung function impairment after achieving microbiological cure and the risk factors associated with it.

METHODS:

This is a prospective observational cohort study conducted in the department of pulmonary medicine in a tertiary care Centre. Our study participants were recruited from February 2018 to February 2019 and were followed up for a period of 6 months. 92 patients were recruited of which 84 patients had pulmonary Tuberculosis and 8 patients had pleural tuberculosis. Spirometry was performed at baseline and complete pulmonary function test at the end of intensive phase and end of treatment. Change in lung function over course of illness and persistent lung function impairment after treatment was analysed. Other parameters like smear conversion, radiological resolution, improvement in quality of life with lung function change was also assessed.

RESULTS:

At baseline, 2nd month and 6th month, 7 patients (8.64%), 5 patients (8.06%) and 6 patients (8.57%) had obstructive ventilatory defect respectively. At the same time points 44(54.32%) patients, 33(53.22%) patients and 31(44.28%) patients had restrictive ventilatory defect. So after treatment completion 37 (52.8%) patients had ventilatory defects of which 31(44.28%) patients had restrictive pattern and 6(8.57%) had and obstructive pattern. The mean improvement in FEV1 % from baseline to 6th month was 5.76±10.56 (p-value <0.001), the mean improvement in FVC% was 5.88±11.78 (p-value <0.001) and TLC% was 4.31± 15.54(p-value 0.03) which were statistically significant. The mean improvement in DLCO% was 1.49±16.94 (p-value 0.49) which was not statistically significant. At 2nd month 33 patients were diagnosed to have restriction by FVC and 29 patients by TLC, indicating 4 were over diagnosed by FVC alone. At 6th month 31 patients were diagnosed to have restriction by FVC and 26 patients by TLC. Out of the 84 pulmonary TB patients 43 had cavity at the time of diagnosis and 11 had residual cavity while completing treatment. The Total chest x-ray score before starting treatment in those with lung function impairment and those who had normal lung function were 44 and 36 respectively (p-value 0.02) and after completing treatment it was 15 and 11 (p-value 0.004). The mean total score in quality of life questionnaire reduced from 41.45 ± 16.92 before treatment to 13.34±7.65 after completing ATT. The difference in total SGRQ score who had normal lung

function and lung function impairment was statistically significant (p-value 0.04).

CONCLUSION:

In our study we conclude that there is significant impairment in lung function in pulmonary TB patients which persist despite microbiological cure. The predominant defect is restriction (44%) and our study showed a lower incidence of obstructive defect (9%) in contrast to many others. Using FVC alone over diagnosed restriction in few patients, hence it is ideal to do TLC to identify true restriction. There is significant improvement in chest x-ray and quality of life with anti-tuberculous treatment which correlates with lung function. Our study results show the need for lung function testing in TB patients. Hence it is advisable to do spirometry atleast while completing treatment, for early identification of those with impaired lung function due to TB.

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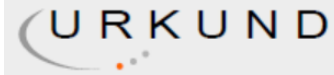

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LIST OF COMMON ABBREVIATIONS USED

- TB – Tuberculosis
- ATT – Anti tuberculous treatment
- LTBI – Latent Tuberculous infection
- MTB – Mycobacterium tuberculosis
- SGRQ – St George's Respiratory Questionnaire
- FVC – Forced Vital Capacity
- FEV1 – Forced Expiratory Volume at 1st second
- DLCO – Diffusion Lung capacity of the Lungs for Carbon monoxide
- TLC – Total Lung capacity
- PTB – Pulmonary TB
- DST – Drug sensitivity testing
- HIV - Human Immunodeficiency Virus
- WHO – World Health Organization
- MMP – Matrix metallaoproteinase
- COPD – Chronic Obstructive Pulmonary Disease
- Th 1& 2 – T helper Lypmphocyte
- PFT – Pulmonary Function Test
- HRQOL – Health Related Quality of Life
- LJ – Lowenstein Jenson

TITLE

THE EFFECT OF APPROPRIATE ANTI TUBERCULOUS THERAPY ON RECOVERY OF PULMONARY AND PLEURAL TUBERCULOSIS AND THE IMPACT OF TUBERCULOSIS ON LUNG FUNCTION AND QUALITY OF LIFE IN NEWLY DIAGNOSED PATIENTS

INTRODUCTION

Tuberculosis is one of the leading causes of death globally and is the single most infectious disease with the highest mortality. In 2017, TB caused an estimated 1.3 million deaths among HIV-negative people and there were an additional 300 000 deaths from TB among HIV-positive people. Also, global estimate is that 10.0 million people developed TB disease in 2017 of which 5.8 million were men, 3.2 million were women, and 1.0 million were children(1) .

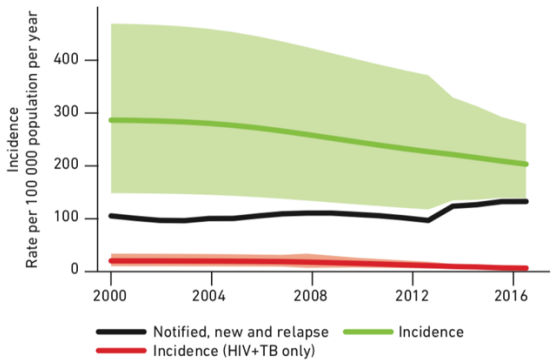

Figure 1: Incidence of TB in India 2017 (1)

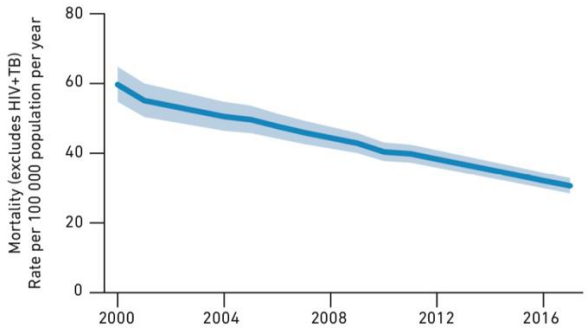

Figure 2: Mortality of TB in India , 2017 (1)

The incidence of TB is 204 per lakh population. The mortality because of TB excluding those with HIV has come down from 60 to 31 per lakh population over last decade as per WHO 2018 TB burden report. Mortality reduction can be attributed to early identification, awareness of drug resistance tuberculosis, better diagnostic modalities and treatment available.

TB is an infectious disease caused by the bacillus Mycobacterium tuberculosis. It typically affects the lungs (pulmonary TB) but can also affect other sites (extrapulmonary TB).

Currently, treatment is based on four drug regimen consisting of Rifampicin, Isoniazid, Pyrazinamide and Ethambutol for drug-sensitive TB and patient specific treatment for Multidrug-resistant tuberculosis. Treatment success rates are above 95% in drug-sensitive TB(2).

In patients infected with M. tuberculosis, whether treated or untreated, a variety of pulmonary and extra-pulmonary sequelae and complications can occur which can be parenchymal, airway involvement or pleural (3). Structural changes lead to obstructive, restrictive, or mixed patterns of impaired pulmonary function. Previous studies in patients with pulmonary tuberculosis (PTB) have demonstrated that 33.3-94.0% of such patients develop impairment in pulmonary function(4) .

Pulmonary impairment after tuberculosis (PIAT) refers to chronic pulmonary function loss that occurs in persons who have achieved microbiologic cure after pulmonary tuberculosis. Patients usually have pulmonary function abnormalities after completing treatment for pulmonary tuberculosis. Patients who are treated for tuberculosis are not routinely evaluated for these permanent changes. During treatment of tuberculosis performing repeat x-ray is considered not essential as per guidelines. Evaluation after a cure is only done for symptomatic patients and on suspicion of re-occurrence. Symptoms of pulmonary impairment are not present in all patients. Symptoms of pulmonary impairment generally do not occur in patients with chronic lung disease until FEV1 has fallen to 50% of normal values (5).Incidence of obstructive and restrictive lung disease post tuberculosis is not a well-established phenomenon and has a varied prevalence according to different studies.

There are no prior Indian studies which look at the trend of lung function change during the course of illness. So our study was designed to capture the change in lung function through the course of illness by following lung function before initiating ATT and after completing treatment which will add valuable information to the existing knowledge.

REVIEW OF LITERATURE

Tuberculosis is caused by the bacteria Mycobacterium tuberculosis. It is one of the oldest diseases known to humans and studies suggest that it could have emerged as early as 70000 years before in Africa(6) . It is one of the leading causes of mortality among infectious diseases. The disease burden of Tuberculosis is high among emerging countries. TB most commonly affects the lungs, followed by lymph nodes. Transmission usually takes place through the airborne spread of droplet nuclei produced by patients with infectious pulmonary TB.

Mycobacteria belong to the family Mycobacteriaceae and the order Actinomycetales.

M. tuberculosis complex comprises eight distinct subgroups, the most common of which is M. tuberculosis (7).It is a thin, rod-shaped, non-spore forming aerobic bacteria, which is not decolorized by acid alcohol, hence called as acid-fast bacilli. This characteristic is due to the high content of mycolic acids, long-chain cross-linked fatty acids, and other cell-wall lipids (8).

Risk factors for TB:

1. Exposure related:

a) Bacillary load and sputum status of index case:

Epidemiological studies have shown that smear positive cases are more infectious than smear negative cases (9). A sputum positive patient can infect approximately 10 individuals per year, and each smear positive case can lead to at least two new cases of TB, of whom at least one will be infectious (10). Espinal and colleagues, in their study of 803 household contacts of 174 index TB patients, studied the effect of HIV on the infectiousness of Mycobacterium tuberculosis. In the sub analysis, odds of TST positivity for contacts with an index case sputum smear grade 1–10 (bacilli per field) was 1.98 and >10 (bacilli per field) was 5.88 compared to 0 (bacilli per field), which clearly shows that being a contact with a patient coughing up higher amount of bacilli was associated with a greater likelihood of having a positive TST (11)

b) Proximity to infectious case:

Close contacts of infectious TB cases including household contacts and caregivers/health care workers are at a higher risk of becoming infected with Mycobacterium tuberculosis and the development of primary active tuberculosis(12) . Morrison and colleagues performed a systematic review of 41 studies to determine the yield of household contact investigation.

They concluded that bacteriologically confirmed and clinically diagnosed were found in 4.5% of contacts investigated. Latent tuberculosis infection was found in 51.4% of contacts investigated. Latent TB was diagnosed by Tuberculin skin testing and the test is limited in its interpretation because of false positive and false negative results(13).

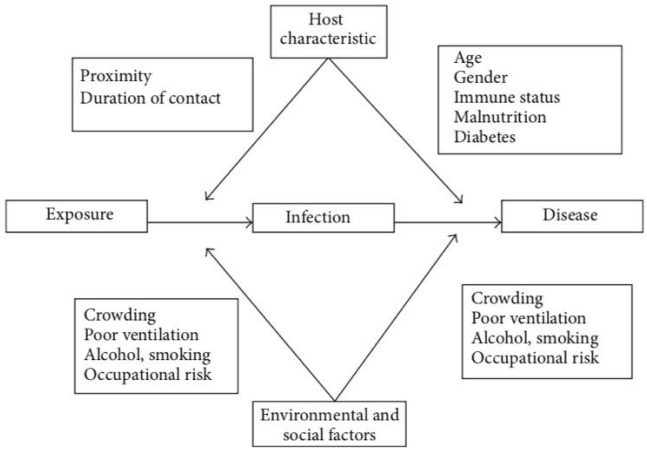

Figure 3: TB risk factors 26

2.Factors related to the individual:

a) Immunocompromised :

Association of TB with HIV has higher mortality and morbidity. HIV infection is the most potent immunosuppressive risk factor for developing active TB(14). HIV coinfection exacerbates the severity of existing TB and also TB coinfection accelerates HIV replication (15).

b) Malnutrition:

Micro and macro deficiency increases the risk of TB because of impaired immune response to the disease causing organism (16) (17). Also TB itself can lead to malnourishment because of decreasing appetite and cachexia (18).

c) Diabetes:

Diabetes has been shown to increase the risk of active TB. It is mainly postulated to be due to impaired immune mechanisms leading to an immunosuppressed state (19). A reverse association where TB can cause glucose intolerance and worsen glycaemic control in subjects with diabetes has also been identified (20). Poor glycemic control is a significant challenge in treatment of TB.

d) Young age:

Children are at higher risk of contracting TB infection and disease. Studies show that disease transmission is as high as 80% on contact with smear-positive cases(21). The majority of the children less than 2 years of age get infected from the household source case, whereas, with children more than 2 years of age, are infected in the community.

3. Socio economic and behavioral

a) Smoking and Alcohol:

Bates and colleagues, in a meta-analysis of 24 studies on the effects of smoking on TB, showed that the relative risk (RR = 2.3–2.7) was high among smokers in developing TB in comparison to nonsmokers. There was clear evidence that smoking is a risk factor for TB infection and disease, with an additional risk of death in persons with active TB (22).

Alcohol is also associated with an increased risk of TB disease. A systematic review of 3 cohorts and 18 case-control studies concluded that the risk of active tuberculosis is increased among people who drink more than 40 g alcohol per day and/or have an alcohol use disorder(23) .

b) Poverty:

TB burden is higher in countries with high poverty and low gradient of income(24). The low socio-economic group is associated with an increased risk of active TB. It is primarily due to a variety of factors including malnutrition, indoor air pollution, alcohol, exposed to crowded, less ventilated places and use of biomass fuels for cooking(25) (26).

Pathophysiology of TB:

In primary TB, when a person with an intact immune system, inhales the Mycobacterium tuberculosis bacilli that happens through droplet infection, the macrophage encounters and kills the bacteria. When the immune system does not kill the bacteria, they signal the production of various Interleukins and pro-inflammatory cytokines. They proliferate within dendritic cells and alveolar macrophages at a rapid rate. This proliferation is mediated by pattern recognition receptors. In TB there is be a detectable cellular response after about 2 - 12 weeks after infection(27) . The primary TB is usually localized and is known as the Ghon's focus, which forms a granuloma in the middle or lower lobe of lung. Ghon's complex is Ghon's focus with hilar or paratracheal adenopathy with pleural reaction. In most infected individuals, Ghon's focus does not progress to diseases. This state is known as latent tuberculosis (28).

In post-primary TB, systemic immunity subverts to produce local susceptibility in the apex of the lung. It begins in the part of lung with the lowest ventilation, perfusion, and then causes abnormality in alveolar macrophages, block the exits and suppress inflammation to further isolate the area with post obstructive pneumonia. This provides a safe place for tuberculous bacilli to drive prolonged accumulation of host lipids and mycobacterial antigens in an otherwise immune person. After many months, the affected lung undergoes caseation necrosis with only a few bacilli. The

necrotic tissue can become fragmented to produce a cavity or hardens to develop the fibro-caseous disease (29).

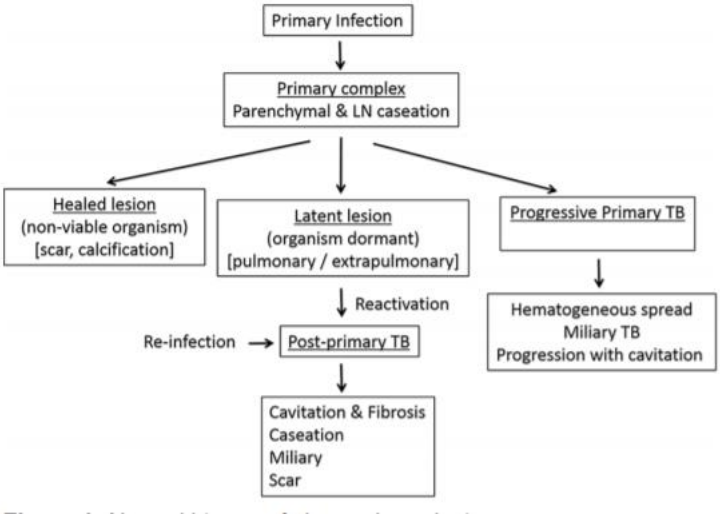

Figure 4 Natural History of TB(30).

Drug-resistant tuberculosis:

Drug-resistant TB is one of the biggest challenges to treatment of TB and ultimately to the elimination and eradication of TB

Multi-Drug Resistant Tuberculosis (MDR-TB):

MDR – TB is resistance to anti-tubercular medications which include at least the two standard anti-tubercular medications namely Isoniazid and Rifampicin. Only25% of MDR cases are due to acquired resistance, whereas the remaining 75% is due to due to direct infection by MDR bacilli (28).

Extensively Drug-Resistant Tuberculosis (XDR- TB):

Mycobacterium which is resistant to at least four of the anti-tubercular drugs including resistance to Rifampicin and Isoniazid, and resistance to any of the two newer drugs which include the Fluoroquinolones (Levofloxacin or Moxifloxacin) and the second line injectable aminoglycosides like Amikacin, Capreomycin, and kanamycin (28).

Diagnosis of TB:

Diagnosis of Tuberculosis requires high suspicion when a patient presents with cough, fever and weight loss for more than 2 weeks duration. In a resource-limited settling above symptoms with chest x-ray showing upper lobe involvement is very likely to be TB, though this is not specific.

Radiological studies:

Chest Xray:

A chest x-ray is one of the first investigations in a proven or suspected case of TB. Chest x-ray alone will over diagnose TB even in endemic areas. The findings are specific but can be atypical in coexisting conditions like HIV or childhood TB. It should be remembered that X-ray is not specific for diagnosing TB (31). In the old era mass miniature X-ray (MMR) was used as

an active case finding tool. However it was later concluded that MMR is not cost effective like sputum smear examination and it tends to over and misdiagnose patients. In Post-primary TB healing occurs with parenchymal scarring and nodules. It is important to determine whether these residual findings are indicative of active disease. Chest X-ray has limited value since it can only establish a lesion and lesion may or may not contain active bacilli(32).

Ralph et all published a simple, validated method to score extent of chest xray involvement in sputum smear positive pulmonary TB patients. This scoring system correlates with baseline clinical and sputum smear severity at the time of diagnosis with response to treatment. The features in chest radiology that predicted the outcome were area of lung involvement and presence of cavitation. Percentage of lung involvement is 0 to 100%. If there is additional cavitation a score of 40 is given. In total with percentage of lung involvement and cavitation the total score ranges from 0 to 140. Other radiological features like size of cavity or mediastinal adenopathy did not correlate with the outcome.

While assessing outcome at 2 months, chest xray scores were statistically and clinically associated with severity of sputum smear at diagnosis ($p<0.001$), lung function, body mass index, quality of life and exercise tolerance ($p<0.02$ for each) (33).

Computer Tomography (CT):

Chest computer tomography is required in cases where a small lesion may have been overlooked by X-ray, equivocal cases and also where complications need to be evaluated(34). But CT doesn't significantly alter the diagnosis or management as demonstration of bacilli is pivotal for diagnosis.

O N Hatipoglu et all looked the features of active pulmonary TB in high resolution CT and identified that "tree-in-bud" appearance (n = 23), centrilobular lesions (n = 29), and macronodules 5-8 mm (n = 22) correlated with active TB. However, in post tuberculosis inactive patients, findings were distortion of bronchovascular structures (n = 32), bronchiectasis (n = 24), emphysema (n = 28) and fibrotic lesions (n = 34). So HRCT was able to differentiate active lesions from inactive ones(35)

Im et all described sixteen different radiological signs on CT, which are tree in bud appearance, centrilobular nodules, poorly defined nodules, cavity, consolidation, bronchial wall thickening, mediastinal adenopathy, bronchiectasis, fibrotic bands, mosaic attenuation, increased attenuation, miliary pattern, emphysematous pattern and pleural effusion(36) .

Indications to do CT are a) In suspected and diagnosed TB patients with negative sputum AFB/ CBNAAT with equivocal chest xray and clinical

profile, as part of complete assessment in patients suspected to have extra thoracic involvement.

b) In diagnosed TB patients - to assess disease activity when there is persistent or worsening lesion on chest x-ray or when any other etiology is suspected to co exist. CT can be done when complications of TB are suspected or for evaluation of suspected post TB sequelae(30).

Microbiological diagnosis:

Samples:

The samples that are usually used in the diagnosis of pulmonary TB are sputum, gastric lavage (in children), bronchoalveolar lavage and lung biopsy specimen. Samples that can be used for diagnosis of Pleural TB are pleural fluid or pleural tissue.

AFB smear microscopy:

In pulmonary TB, sputum smear is the most rapid and inexpensive diagnostic tool. Sputum examination is done by direct microscopy by either light microscope using Ziehl Neelson technique which demonstrates acid fast bacilli (AFB) or by LED Fluroscence microsocpy . LED-based microscopy was introduced in 2009 by WHO. WHO recommended that laboratories where fluorescence microscopy is currently used should be replaced by LED

microscopy, and in laboratories using Ziehl-Neelsen light microscopy, LED microscopy to be phased in as an alternative(37). Sputum microscopy cannot distinguish viable from non-viable organisms. It cannot differentiate mycobacterial species. Sensitivity of AFB smear is reduced in advanced HIV and extra-pulmonary TB(38). Microscopy is present in all primary care centers and the inconvenience of 3 samples has been reduced to two by WHO in 2007(39).Well trained technician and two good samples of sputum can detect up to 95% of smear-positive cases(40) .Though microscopy is relatively specific it has variable sensitivity and cannot identify the drug-resistant organisms.

Same-day sputum smear microscopy is as accurate as standard smear microscopy. Meta-analysis by Davis et all showed that standard 2 days examination of sputum AFB smear and same day 2 smear examination had same sensitivity (64% for standard microscopy vs 63% for same-day microscopy) and also similar specificity(41). The yield of AFB smear on pleural fluid is less than 10% (42).

No of bacilli observed	Estimated concentration of bacill/ml sputum	Probability of a positive result
0 in 100 or more fields	< 1000	<10%
1-2 in 300 fields	5000 – 10,000	50%
1-9 in 100 fields	^ 30,000	80%
1-9 in 10 fields	^50,000	90%
1-9 per field	^100,000	96.2%
10 or more/field	^500,000	99.5%

Table 1 AFB smear load (43)

Mycobacterial culture:

Culture provides accurate diagnosis and valuable information on drug susceptibility and remains the gold standard. On Comparison with sputum smear microscopy which requires about 10,000 AFB's per ml of sputum to be positive, sputum culture requires as less as 100 bacilli per ml. Thus sputum culture has a higher sensitivity than sputum microscopy.

Sputum culture can identify mycobacterial species and drug resistance pattern(39). Different culture methods are Lowenstein Jensen medium which is egg based, Middlebrook 7H10 or 7H11 which is agar based and Middlebrook 7H12 and other commercially available broths which are Liquid medium.

Advantage of liquid medium is that it is less time consuming (usually 1 to 3 weeks) compared to solid medium which is usually four to eight weeks. In 2007 WHO introduced Liquid media for culture and DST and recommended that as a step-wise approach liquid medium for culture and DST in middle-income and low-income countries(37).

In smear negative patients the yield of MGIT was 29.7% compared with LJ medium which was 22.8%. Of the 162 smear positive patients 151 (93.2%) were positive for MGIT, 144 (88.9%) were positive on LJ and 138 were positive on both. However contamination rates were higher for MGIT (16.7%) compared to LJ (9.3%). In terms of yield and rapid results Mycobacterium Growth Indicator Tube (MGIT) is superior to Löwenstein-Jensen (LJ) medium with however higher cost and more contamination rate (44). The diagnostic yield of conventional culture in pleural TB ranges between 12 to 70%(42).

The appearance of MTB on egg-based media like LJ media is a general rough and dry appearing colony simulating breadcrumbs and is non-pigmented. On agar based media like middle brook medium, they appear to be flat, dry with rough and irregular edges.

Molecular methods:

XPERT:

It is a cartridge-based Nucleic Acid Amplification test and the cartridge is pre-loaded with all required reagents to run the test. It takes only two hours to confirm the diagnosis and also to give DST on rifampicin sensitivity by locating the rpo B gene. The Meta analysis by WHO showed pooled sensitivity for detection of pulmonary TB was 88% and the pooled specificity was 99%. When Xpert is used as additional test after a smear negative smear-microscopy, then the pooled sensitivity was noted to be 68% and the pooled specificity was 99% (45) . The pooled sensitivity of pleural fluid Xpert while comparing to pleural fluid culture is 51.4%(46).

Boeheme et al assessed the performance of sputum XPERT. In culture positive patients the sensitivity of XPERT for the diagnosis of TB who were AFB smear positive was 98.2% and those who were AFB smear negative was 72.5%. The specificity was 99.2%. (47). Sputum XPERT gives a rapid diagnosis of pulmonary TB and information on INH and rifamipicin resistance but it provides no help in choosing the antituberculous treatment.

In March 2017 a next generation test was introduced which was called as GeneXpert Ultra/Ultra. Sensitivity of Ultra is higher than Xpert in general

and also in smear negative culture positive patients, children, HIV infected patients and in extrapulmonary TB. However the specificity was found to be low compared to Xpert(48).

Line probe assay:

To decrease the mortality and morbidity and also to prevent emergence of new infections due to drug resistant TB, rapid diagnostic tests are needed. The turnaround time of conventional phenotypic solid assays are around eight to twelve weeks. Resistance to isoniazid is due to mutations in katG predominately, followed by mutations in InhA active site and also in the promoter region of ahp C. Mutations in the rpo B region are found in about 96% of rifampicin-resistant M. tuberculosis specimen (49). Following multiple meta-analysis WHO recommended that commercial line probe assays can be used as the initial test instead of phenotypic culture-based DST in smear positive patients. However it is not recommended to replace conventional culture which is still required to diagnose resistance to other ATT drugs(48).

Pulmonary impairment after tuberculosis:

Patients with pulmonary TB develop structural changes in lung which can result in alterations in lung function during illness and after obtaining microbiological cure. Changes can be pleural, parenchyma scarring or

bronchial stenosis. The lung function impairment can persist even after attaining microbiological cure following treatment (50). According to various Studies it varies between a range of 32-80%(51). TB patients are not routinely screened to identify these changes. Impairment can present as obstructive ventilatory defect which can be reversible or irreversible, restrictive or mixed ventilator defect. Obstructive airway defect is related to inability to exhale air completely which could be due to narrowing of airways which is induced by inflammation. Whereas restrictive defect which is inability to inhale air completely which could be due to extensive fibrosis of lung parenchyma. Majority of the studies has identified obstructive defects as the predominant defect. A metanalysis by Allwood et all proved a significant association with Odds ratio of 1.37 -2.94 between pulmonary TB and chronic airflow obstruction (52).

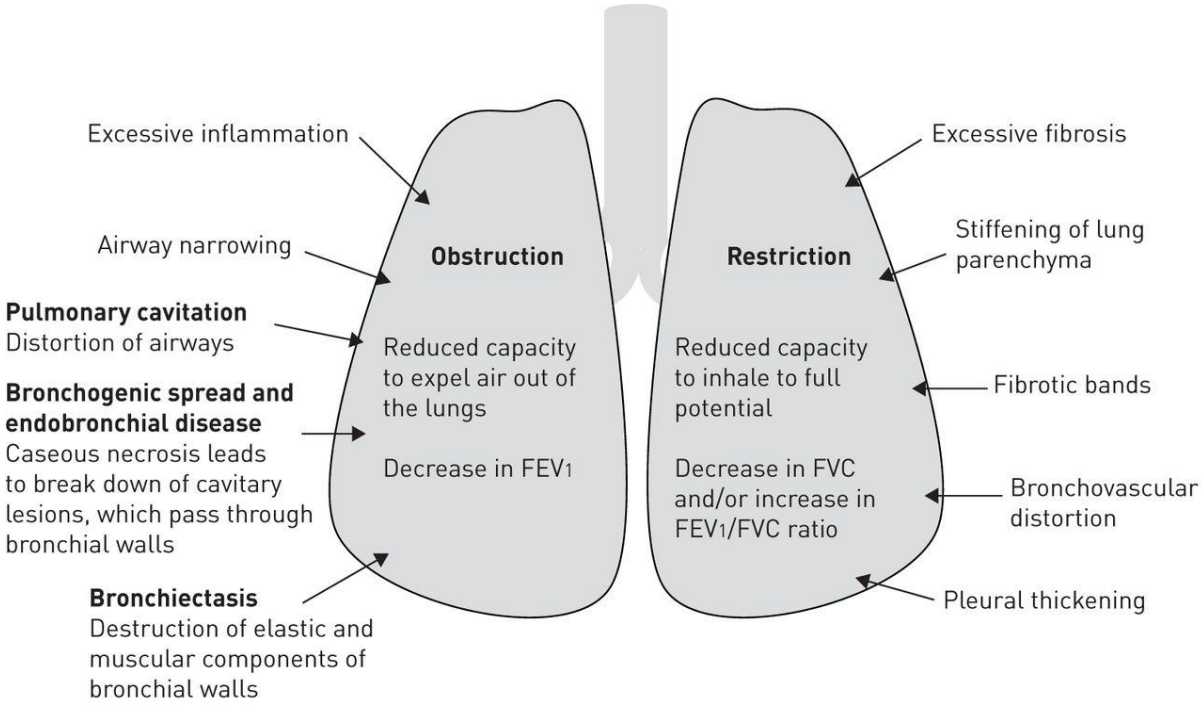

Figure 5 Mechanisms of pulmonary function impairment in Tuberculosis(53)

Obstructive ventilatory defect in tuberculosis:

Post TB obstructive ventilatory defect can be reversible as in asthma or irreversible as in chronic obstructive pulmonary disease. GOLD 2019 defines airflow limitation as post bronchodilator FEV1/FVC less than 0.7 (52).

TB and asthma:

Mechanism proposed for asthma like changes, post TB is immunological**.** The T helper lymphocyte(Th1) subgroup plays the major role in development of TB and the Th2 subgroup of lymphocytes in bronchial asthma. After treatment with antituberculous drugs Th1 levels decreases. A subset of these patients develops airway obstruction by Th2 lymphocytes which manifests as asthma on aggravation(54). Hypothesis states that Th1 and Th2 levels are not elevated together. So asthma and active TB do not attain the maximum activity simultaneously.

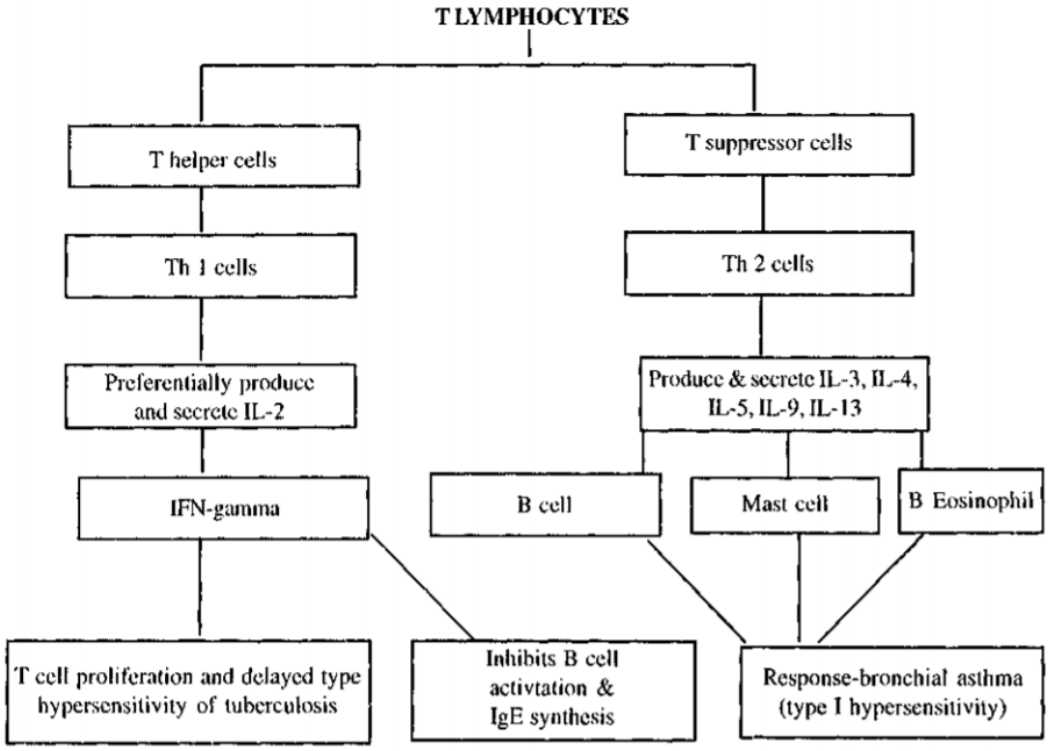

Figure 6 Role of Th1 and Th2 in asthma and tuberculosis(55)

The study by Garg et al looked at association between TB and asthma. They included 69 patients with concomitant TB and asthma, of which 48 (69.6 %) patients developed asthma after TB and 21(30.4%) developed TB after asthma. 25 out of the 48 who developed asthma after TB did so within 5 years of antituberculous treatment and only 2 out of 48 had family history of asthma(56). Another study which was done on 55 patients who were diagnosed to have pulmonary tuberculosis and completed the course of ATT with post TB asthma showed that 50% of them developed asthma within first one year and rest within 10 years. 25% of patients had family history of asthma (55).

TB and COPD:

Different mechanisms proposed for the development of chronic obstructive pulmonary disease(COPD) after TB disease as characterized by irreversible obstructive ventilatory defect in PFT are structural damage of airways, cavitation, bulla formation, bronchiolar narrowing, extensive fibrosis, bronchiolitis obliterans (57) (54). Studies show an association of matrix-metalloproteinase system (MMPs) in development of obstructive airway defect. Destruction of extra cellular matrix such as collagen and elastin by MMPs is essential for the formation of cavitation in TB and MMPs are likely to play a role in TB pathogenesis. Similarly in COPD degradation of Type 1 collagen and elastin by MMPs is considered to cause airway remodeling(58). Destruction caused by MMPs in TB and COPD and the remodeling of ECM plays and important role in development of COPD after TB disease. Other mechanism considered is latent intracellular mycobacterial infection leading to dysregulation of macrophages. It is proven that lung macrophages kill bacteria and their dysregulation has an important role in development of chronic airflow obstruction after TB. So it is considered that latent mycobacteria in lung macrophages leads to maintenance of inflammation leading to airway remodelling (59) (60) (61) . It appears that the susceptibility to develop active TB and COPD comprises a complex interaction between the genetic and environment components. The outcome relies on the net result of imbalance between proteases anti-protease imbalance, and oxidative stress(62).

The PLATINO study which was a multicentre trial done in 5 centres in Latin America evaluated the association between airflow obstruction and Tuberculosis. Of the total 5571 subjects included 132(2.4%) had a past history of Tuberculosis. Among those with a past history of TB the prevalence of airflow obstruction was 30.7% while compared to those without past history of TB, 13.9%. Also the association of TB was significant with FEV1 than FVC. PLATINO study concluded that there is association between history of Tuberculosis and airflow obstruction(63).

BOLD study which is a multicentral trial on COPD patients had data on patients with history of TB. The adjusted odds ratio of participants with self-reported history of TB with restrictive pattern and obstructive pattern were 2.13 and 2.51 respectively(61).

Case control study by Agarwal et al looked at the prevalence of TB-associated COPD in patients presenting to OPD among COPD patients. Stable COPD patients and healthy controls were enrolled in equal number. There was past history of pulmonary tuberculosis in 24 out of 74 patients (32.4%). While comparing with controls the odds of history of previous pulmonary TB in COPD patients was noted to be 3.96 (95% confidence interval: 1.64–9.55 and *P* value of 0.002) while comparing to controls(64).

Yakar et al analysed 598 patients who were hospitalized for exacerbation of COPD and they were divided into two groups based on presence or absence of TB history. Out of 598, 93 patients (15%) gave past history of TB. Those patients with history of TB were 4 years younger compared to the other group with *P* value of 0.002. Other findings noted in the group with past history of TB are earlier COPD diagnosis by 4 years, higher hospitalization rate and lower FEV1. And the study concluded that TB influences the natural history of COPD (65).

Another recent study which recruited 172 patients from CTRIUMPH study which is part of RePORT India Tb consortium detected airflow obstruction in 42(24%) patients and restrictive spirometric pattern in 89 (52%) patients(66). Study by Plit et all which included 76 TB patients showed that with anti tuberculous treatment there was improvement in lung function in 54% but there was residual airflow obstruction in 28% and restrictive defect in 24%(67).

The study by Akkara et all which included 264 patients who completed treatment for TB reported a high incidence of obstructive defect. Obstructive airway disease was seen in 223 (86.8%) patients with 64(28.7%) having combined restrictive ventilatory defect. This study showed a very high incidence of obstructive airway disease post TB compared to the other studies(51).

Restrictive ventilatory defect in tuberculosis:

According to European Respiratory Society restrictive pattern in spirometry is defined as either an increase in FEV/FVC ratio and or decrease in forced vital capacity (FVC)(68). Scarring leading to loss of lung parenchyma in TB during and post ATT leads to restrictive pattern in spirometry.

Case control study done in 107 PTB patients and 210 Latent TB (LTBI) patients showed any abnormality in 59% of Tb patients and 20% of latent TB patients. Restrictive pattern was most common in both groups with 31% in TB group and 15% in LTBI group. Patients in TB group were 5.4 times more likely to have abnormal lung function than LTBI group(69).

Study by Plit et al howed that there was significant improvement in FEV1during treatment implying that successful therapy prevents restrictive defect more than obstructive ventilatory defect(67). Acccording to Gupte et al study, diabetic patients treated for Pulmonary TB, had lower FVC and the Odds of developing restrictive ventilatory defect was higher (66). However such relation was not found in any other studies.

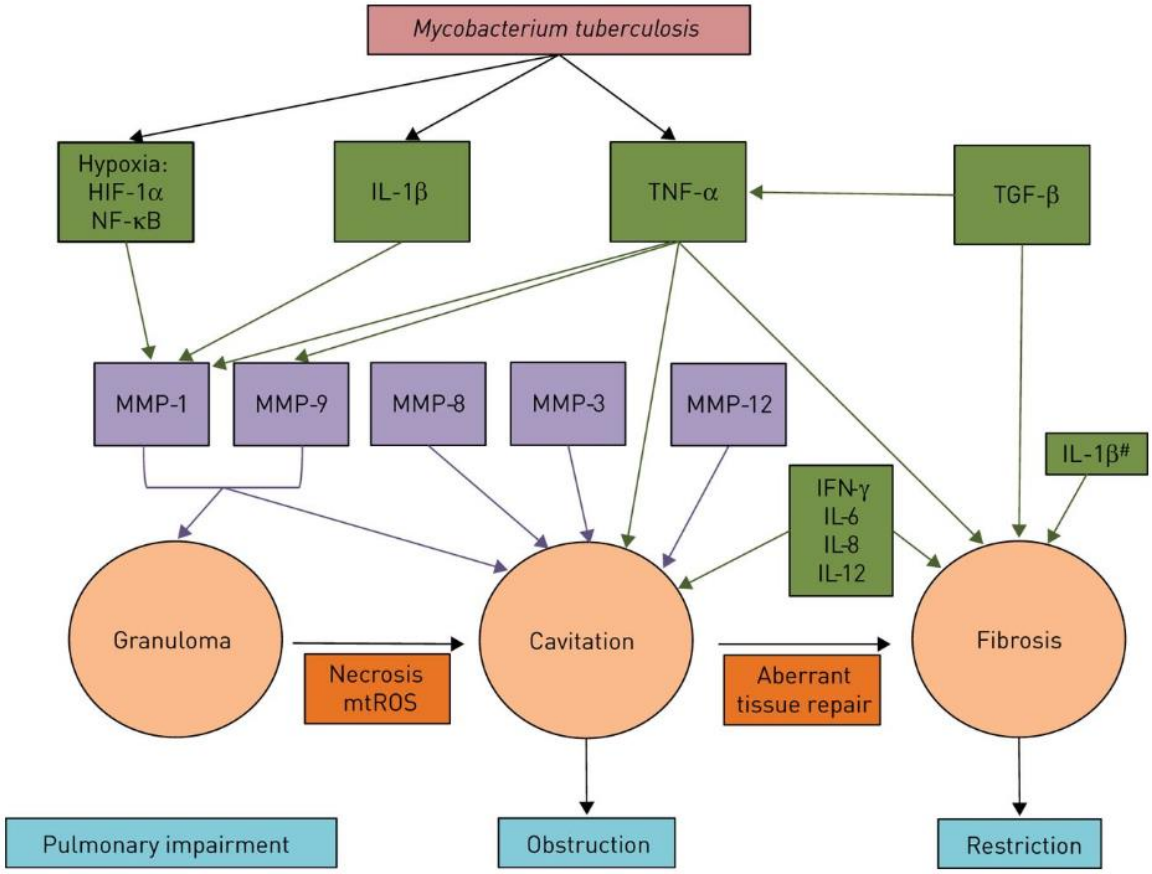

Figure 7 Lung function impairment and immunological modulators (53)

Diffusion lung capacity and TB:

The effect of TB on Diffusion lung capacity for carbon monoxide is not well studied. In 159 TB patients who had either fibrocavernous, focal or infiltrative disease, DLCO and DLCO/VA with other parameters was analysed. In patients with fibrocavernous and disseminated TB half of them had decrease in DLCO and in those with focal disease only one fifth had decrease in DLCO. The important factor causing decrease in DLCO in patients with fibrocavernous and disseminated disease is reduction in effective alveolar volume which leads to reduction in respiratory surface of the lung. The main

cause of infiltrative tuberculosis was reduction in alveolocapillary membrane permeability (70).

Kiryukhina at al evaluated the effect of COPD and smoking on DLCO in TB patients and divided the patients into 3 groups as non-smokers, smokers without COPD and COPD. DLCO was moderately decreased in non -smokers and smokers without COPD. Most significant decrease in DLCO was noted in patients with COPD and TB (71). There is not much evidence available for association between TB and DLCO.

St George's Respiratory Questionnaire:

SGRQ questionnaire which principally has 50 items which was designed to measure health impairment in patients with asthma and COPD, which was later validated for use in bronchiectasis and post tuberculosis. It is in two parts. Part I (1-7 are Summed) produces the Symptoms score, and Part 2(Questions 8-14) the Activity and Impacts scores. A Total score is also produced(72).

SYMPTOMS COMPONENT: This consists of all the questions in Part 1and includes Questions 1-7 of single response.

ACTIVITY COMPONENT: This is calculated from the summed weights for the positive responses to items in questions 9 and 12.

IMPACTS COMPONENT: This is calculated from Questions 8, 10, 11, 13, 14 in Part 2 of the questionnaire and weights for all positive responses to items in Questions 10, 11, 13 are summed together with the responses to the single item that should have been checked in Questions 8 and 14. In the case of multiple responses to either of these items, the average weight for the item should be calculated.

TOTAL SCORE: The Total score is calculated by summing the weights to all the positive responses in each component.

The study by Pasipanodya et al on assessing quality of health in patients treated for pulmonary tuberculosis, SGRQ scoring has been used in diverse population microbiologically cured of tuberculosis. Over 15 months, 313 subjects completed the SGRQ tool. The SGRQ was found to be valid and reliable in the study population. They concluded in their study that the SGRQ is a valid measure to distinguish different levels of impaired health in persons with a history of PTB and there are substantial health differences in these subjects and a similar comparison group. Patients with microbiologically cured PTB had a mean 13% lower SGRQ score than those with similar risk factors. So a supporting care with more aggressive treatment of LTBI is essential with other disease preventing strategies worldwide(73).

In Banu Rekha et al's study the long term status of sputum positive pulmonary TB patients successfully treated with short course chemotherapy

was assessed with pulmonary function tests (PFT) and St Georges respiratory questionnaire (SGRQ) was used to assess the (HRQoL) health related quality of life. Among the investigated, 58 (29%) had persistent respiratory symptoms; 170(86%) had radiological sequelae but none had active disease. Abnormal PFT was observed in 96 (65%) with predominantly restrictive type of disease in 66(45%). The SGRQ scores for activity and impact were high implying impairment in HRQoL. The patients with a FEV1 % Pred. of <80% had high SGRQ scores implying poor quality of life though it did not attain statistical significance in this study. The major limitation they had was the observations were not be confined to TB sequelae alone but also due to the aging and also other health related factors in those patients. So they concluded that their findings suggest that the scores of the treated PTB patients were high when compared to the general population. Similar to earlier SGRQ studies in PTB patients, the score for impact was lower than that of symptom and activity. The scores were less when compared to patients with other respiratory diseases like interstitial lung disease, COPD or bronchiectasis. These findings suggest that HRQoL among treated PTB patients was suboptimal when compared to the general population, but better when compared to other respiratory diseases(74).

The study by Vijay Nair et al was done on 432 patients who were treated for PTB. Their health status was assessed with Chest radiographs which was analyzed and ranked according to Willcox into three degrees, pulmonary function test was done and Marathi version of St. George's Respiratory

Questionnaire [SGRQ] was used to assess the quality of life. The predominant lung function abnormality was restrictive type of disease in 155 (35%) patients followed by mixed pattern in 90 (20.3%) and obstructive in 46 (10.4%) patients. St Georges Respiratory Questionnaire (SGRQ) scores were higher in the study subjects. The mean SGRQ scores for symptom, activity and impact were 22.44, 33.02 and 19.44 respectively. They concluded that patients who have suffered from pulmonary tuberculosis have poor quality of life scores. Health related quality of life scores (SGRQ) had good correlation with chest x-ray findings and spirometric analysis. So they have advised that all patients post pulmonary tuberculosis should undergo pulmonary rehabilitation for better quality of life(75).

The study by Chushkin Mchushkin et al, the aim of which was to assess the usefulness St. George's Respiratory Questionnaire (SGRQ) for predicting low lung function in patients after treatment of pulmonary tuberculosis, so investigated on 226 patients older than 40 years who were cured for pulmonary tuberculosis (145 males and 81 females). Quality of Life was studied by SGRQ and pulmonary function was studied by spirometry. Receiver Operating Characteristic (ROC) curve analysis was used for assessment of sensitivity and specificity. Total SGRQ of 29% may be the best cut-off in low pulmonary function detection. Higher Total SGRQ score was associated with higher probability of low pulmonary function(76).

Preventive methods can be employed to prevent patients developing lung function impairment due to TB. Primary prevention is by preventing TB infection. Secondary prevention is by preventing patients with latent TB developing active TB. Tertiary prevention is by proper treatment for TB patients which will reduce residual lung damage(50).

In prior studies which looked at lung function impairment in TB patients, spirometry was done after treatment completion and most of them showed a higher rate of obstructive ventilatory defect. But our study aimed at finding the change in lung function through the course of illness by following lung function before initiating ATT and after completing treatment which will add valuable information to the existing knowledge.

MATERIAL AND METHODS

Aim and objectives:

Aim:

To study the Impact of Pulmonary and Pleural Tuberculosis on Pulmonary function and Quality of Life(QOL) in newly diagnosed patients and effect of appropriate Anti tuberculosis treatment on their recovery**.**

Objectives:

Primary Objective:

To assess the change in pulmonary function in pulmonary and pleural tuberculosis (TB) patients on anti-tuberculosis therapy (ATT) from the time of diagnosis to treatment completion.

Secondary Objectives:

- To assess the risk factors associated with improvement or persistence and worsening of pulmonary function impairment in TB patients on ATT
- To estimate the percentage of patients developing persistent pulmonary function impairment at treatment completion with microbiological cure.

- To correlate time to smear/culture conversion with pulmonary function impairment
- To correlate lung function impairment with initial and residual radiological impairment
- To assess change in quality of life with treatment by SGRQ questionnaire and correlate with lung function.

Study design:

Prospective Cohort study

Study Setting:

- Outpatient department and Inpatient department of Pulmonary Medicine and DOTS clinic, Christian Medical college, Vellore, a tertiary care hospital in Tamilnadu, South India.
- Recruitment was done from February 2018 to February 2019.
- Institutional review board and ethical clearance obtained. IRB min no:11153.

Participants:

Inclusion Criteria:

Newly diagnosed Sputum smear AFB positive or Sputum XPERT positive

Newly diagnosed Pleural TB – Histo-pathology /Tissue smear/AFB/Culture positive

Age : >18 years

Exclusion criteria:

Age <18 years

Pregnancy

Active hemoptysis

Underlying lung pathology (ILD, COPD, asthma)

MDR and XDR TB

Uncontrolled hypertension

Bleeding disorders

Psychiatric illness

Patients not able to perform spirometry (chest or abdominal pain/stress in continence)

Recent surgery/MI (I month)/pneumothorax

Non adherence to treatment

Not willing to give consent

Method:

It is a prospective, observational cohort study in which all consecutive newly diagnosed pulmonary and pleural tuberculosis patients were screened and those who were eligible according to study protocol were included.

Pulmonary tuberculosis was diagnosed based on clinico-radiological and microbiological evidence (Xpert or AFB smear) or histopathology from lung biopsy specimen. Pleural Tuberculosis was diagnosed based on either Pleural fluid analysis(Xpert or AFB smear) or Histopathology consistent with TB. Basic demographic details, comorbidities and details of symptomatology were obtained from the patients using CRF. Patients were followed up at 2nd month after completion of intensive phase and 6th month at the time of treatment completion.

Sputum AFB smear was categorized into None, scanty, +1, +2,+3 . Xpert TB PCR of the sputum was categorized into Very low, low, moderate and heavy categories based on our Microbiology lab reports. Sputum culture done by either MGIT or LJ culture was classified as growth present or no growth and the sensitivity pattern was analysed. If any resistance pattern was noted in the culture during follow up, those patients were excluded from the study.

Anemia was diagnosed and severity was classified based on WHO guidelines. In women, normal is 12g/dl or more, Mild anemia is 11-11.9g/dl, Moderate anemia is 8-10.9g/dl and severe anemia as less than 8g/dl. In men, normal is 13 g/dl or more, Mild anemia is 11-12.9 g/dl, Moderate anemia is 8-10.9 g/dl and Severe anaemia is< 8 g/dl (77) . Diabetes was diagnosed based on HbA1c cut off by American Diabetes Association as normal when less than

5.7, Pre-diabetic between 5.7 – 6.4% and diabetic when more than > 6.5% (ref)(78). Body mass index (BMI) was classified based on International association for study of obestity, the Asia perspective (79). Underweight less than 18.5kg/m2, Normal between 18.5-22.4 kg/m2 , Overweight between 22.4 to 24.9 and Obesity more than 25 kg/m2.

Chest xray Scoring:

Scoring system used was adapted from Ralph et all in 2010 for use by the RePORT consortium Investigators(33) (80). The scoring is as follows:

- Percentage of lung involved was given a score of 0-100%
- If cavitation was present a score of 40 was added
- Total score ranges from 0 to 140.

Patient's chest x-ray score at baseline was compared with 2nd month and end of treatment for improvement. Radiological resolution was compared with lung function.

CHEST X-RAY FORM

Participant ID: ☐☐☐-☐☐☐☐☐-☐Visit Date: ☐☐-☐☐☐-☐☐☐☐

D D M O N Y Y Y Y

Site ID: ☐☐☐

Visit Type:☐Baseline ☐Month 2☐End of TX

CHEST X-RAY	☐**Not done, participant pregnant** ☐**Not done, other reason**

Date of Chest X-Ray: ☐☐-☐☐☐-☐☐☐☐

D D M O N Y Y Y Y

Chest X-Ray Findings:

		Right	Left
Lung Opacity (Shadows)	Upper Zone (Apex to anterior end of 2nd rib)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)

	Mid Zone (2^{nd} to 4^{th} rib)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
	Lower Zone (Anterior end of 4^{th} rib to diaphragm)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
Mediastinal Adenopathy		☐Present ☐Absent	☐Present ☐Absent
Pleural Effusion		☐Present ☐Absent	☐Present ☐Absent

Table 2 Chest Xray Form

3.Chest X-Ray Score

3a. Percentage of lung affected: ☐☐☐%

3b. Is cavitation present? ☐ Yes, 40 points ☐ No, 0 points

3c. Score (3a + 3b) ☐☐☐points ***(range: 0 – 140 points)***

Pulmonary function test:

After including the patients in this study spirometry was performed in a negative pressure room with technician wearing N95 mask and other protective measures to prevent transmission. Only post bronchodilator values were obtained to reduce the risk of transmission. At 2nd month and end of treatment after confirming sputum smear conversion, complete PFT including spirometry, diffusion lung capacity for carbon monoxide and lung volumes was performed and standard methods were followed as per ATS guidelines for acceptability and reproducibility.

Spirometry:

Spirometry was done using the JAEGER MasterScreen PFT system, CareFusion Respiratory Care, USA and standard methods followed as per ATS guidelines for acceptability and reproducibility (81). Measured parameters include: Forced expiratory volume in one second (FEV1), Forced vital capacity (FVC), FEV1/FVC ratio, Maximum mid expiratory flow (MMEF), Peak expiratory flow rate (PEFR)

Lung volumes:

Lung volumes was done by closed circuit helium method using the JAEGER Master Screen PFT system, Care Fusion Respiratory Care, USA and standard methods followed as per ATS guidelines for acceptability and reproducibility. It was ensured that the volume and gas calibration was done. It uses a closed, rebreathing circuit in which measured volume of 9% of He and 30 - 35% of O2 is filled in rebreathing bag and the initial concentration of helium was measured. Wearing nose clips the patient was asked to breathe normally and once the tidal volume regular sequence was attained the patient was connected to the helium air mixture at the end of normal exhalation. Then patient was asked to breathe out slowly and completely till the maximum to measure ERV and ask to continue to breathe normally till the equilibrium of helium concentration is attained between the lung and the system.

DLCO:

Diffusion capacity for carbon monoxide was done by single breath test using the JAEGER Master Screen PFT system, CareFusion Respiratory Care, USA and standard methods followed as per ATS guidelines for acceptability and reproducibility Volume calibration and gas calibration was done. The patient was asked to breath normally and to breath out slowly and completely till the maximum(ERV). Then he/she was asked to inhale rapidly of 0.3% CO

and 10% He in air gas mixture to the maximum and hold the breath for 9 – 11 sec and then to exhale smoothly till the alveolar sample is collected for analysis.

Prediction Equations:

The predicted values for FEV1 and FVC were calculated based on Indian prediction equations for different ethnicity and sex.

South India:

For South Indians equation by George D'souza et al. "Prediction equation for the Southern Indian population in 2016-17", under the aegis of the Indian Council of Medical Research (ICMR) (unpublished) was used.

(H) height (A) age weight

Forced Vital Capacity (Male) = -5.218+0.061*H-0.021*A-0.006*W

Forced Vital Capacity (Female)= $(-0.343+0.014*H-0.005*A)^2$

Forced Expiratory Volume in 1sec (Male)=-2.464+0.039*H-0.028*A

Forced Expiratory Volume in 1sec(Female) = -2.454+0.034*H-0.018*A

North India:

"Prediction Equations for Spirometry in Adults from Northern India" by S.K. Chhabra et al was used.

Forced Vital Capacity (Male) = -5.048-0.014×age+0.054×ht +0.006×wt

Forced Vital Capacity (Female)= 20.07-0.010×age-0.261×ht+0.000972×ht2

Forced Expiratory Volume in 1sec (Male)= -3.682-0.024×age+0.046×ht

Forced Expiratory Volume in 1sec(Female) = -2.267-0.019×age+0.033×ht

East India:

For eastern population and those from overseas (Bangladesh) the equation used was "Reference equation for spirometry interpretation for Eastern India" by Dasgupta et al.

Forced Vital Capacity (Male) = –2.5370+ (–0.0211* age) + (0.0418*height)

Forced Vital Capacity (Female)= 0.0972+ (–0.0186* age) + (0.0216* height)

Forced Expiratory Volume in 1sec (Male)= –1.7649+ (–0.0218* age) + (0.0337* height)

Forced Expiratory Volume in 1sec(Female) = 0.0381+ (–0.0197* age) + (0.0196* height)

No patients belonged to western part of India in this study.

Interpretation:

Based on Indian Spirometry guidelines 2019 and Interpretive strategies of lung function test by ATS/ERS, pulmonary function test was interpreted (64) (82). Post

bronchodilator FEV1/FVC less than 70% was classified as obstruction and more than 70% as normal or restriction. The severity of obstruction and restriction was classified based on FEV1% as, Normal ≥ 80% , Mild - ≥70%-79%, Moderate-50%–69%, Severe - <50(64). DLCO was classified as normal - ≥ 80% , Mild - ≥ 60% -79%, Moderate -40–59% , Severe <40% (82). TLC was classified as Normal - ≥ 80 %, Mild - 65 -79 %, Moderate – 50 -64% , Severe - < 50% (usual practice).

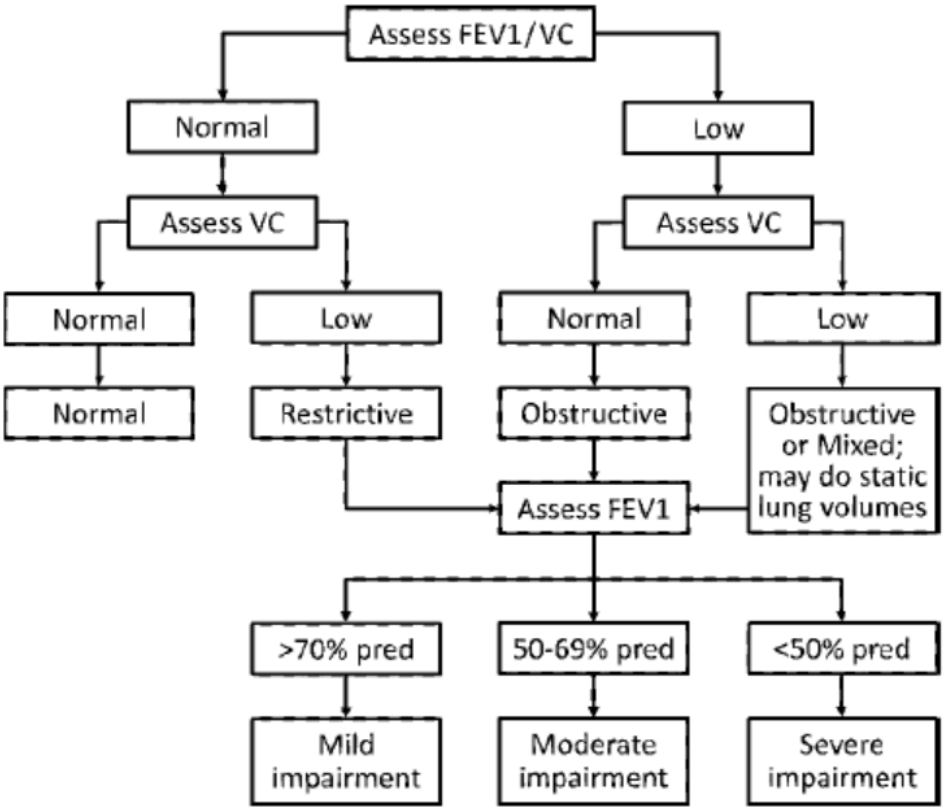

Figure 8 Interpretation of spirometry (64)

St George's Respiratory Questionnaire:

SGRQ questionnaire in native language was administered to the patients and were asked to fill at baseline and follow up visits. They were seated comfortably and any doubt regarding the question was clarified. Questions were under 3 domains, symptom, activity and impact. The answers provided the patient was entered in SGRQ calculator and a total score was generated. Individual domain and total score change was assessed from baseline to treatment completion and also compared with lung function.

Detailed diagrammatic Algorithm of the study

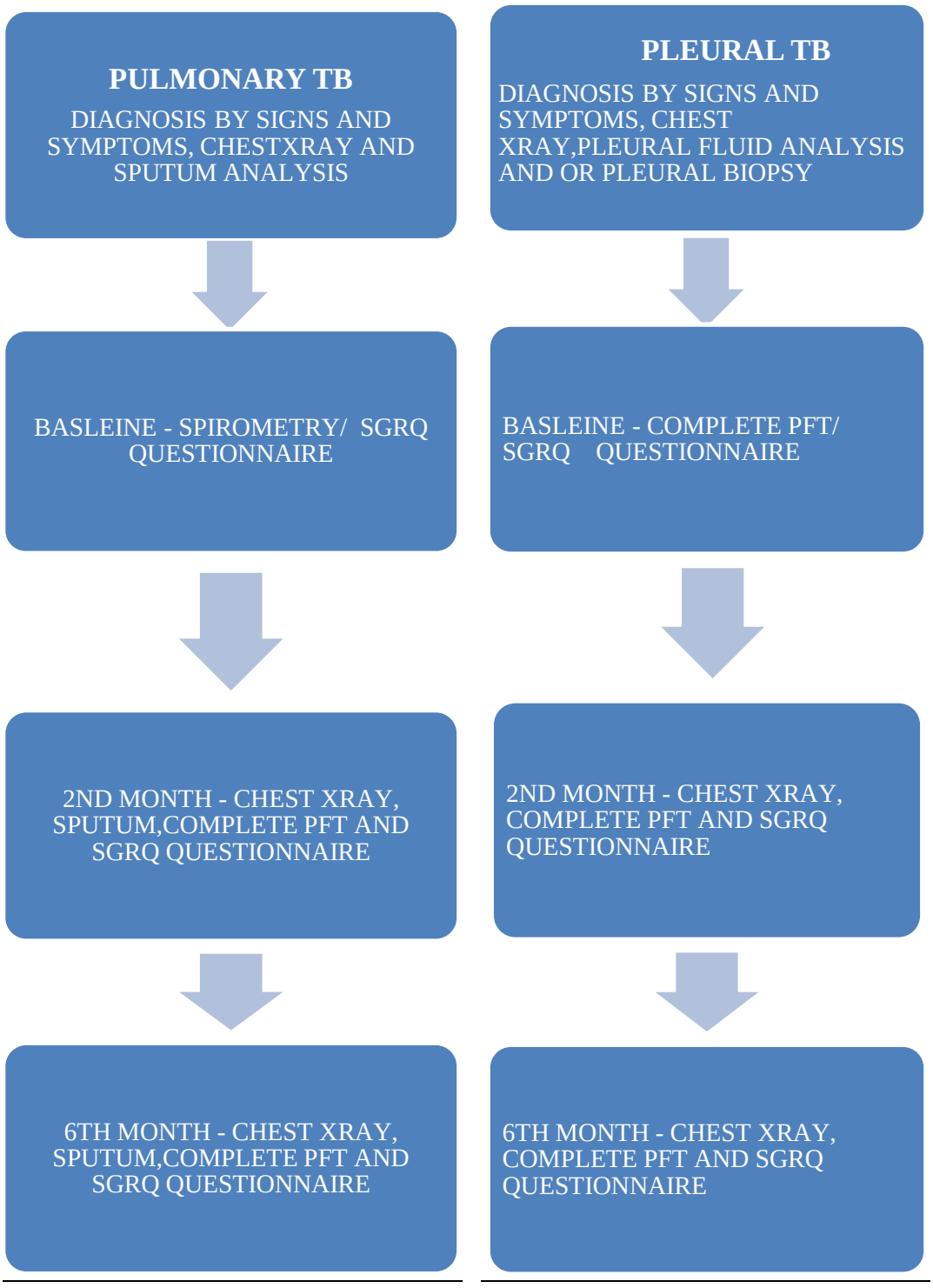

Table 3 Study protocol

Sample size calculation

Sample size calculated based on the study – pulmonary tuberculosis, impaired lung function, disability and quality of life in a high – burden setting

Power Paired proportions .39 .25, corr(.5)

Estimated sample size for a two-sample paired-proportions test Large-sample McNemar's test Ho: p+1 = p1+ versus Ha: p+1 != p1+

Study parameters:

alpha = 0.0500

power = 0.8000

delta = -0.1400 (difference) p1+ = 0.3900 (FEV1 at diagnosis) p+1 = 0.2500 (FEV1 at treatment completion)

corr = 0.5000

Estimated sample size : N = 92

Software used: stata 13.0

Quantitative variables:

FEV1, FVC, FEV1/FVC, TLC and DLCO. SGRQ questionnaire under three domains symptoms, activity and impact.

Statistical methods:

Data entry was done using EpiData. Statistical analysis was done using STATA/IC 15.0 software. Descriptive statistics was reported with Mean±SD for normally distributed variables and Median (IQR) for skewed variables and Frequency and percentage was reported for categorical variables.

Data entry and statistical analysis:

All data were entered into the clinical proforma and subsequently entered into EpiData software. Uni-variate analysis for the continuous variables was reported using Mean±SD with Independent t-test (for two unpaired groups) and one-way anova (3 or more unmatched groups), for normally distributed variables and reported Median (IQR) with Mann-Whitney test (for two unpaired groups) and Kruskal-wallis test (3 or more unmatched groups) for skewed variables (i.e., not normally distributed variables). Frequency and percentage was reported for categorical variables along with chi-square p-value to check the association between the categorical variables. Comparison between the pre and post (two paired groups) analysis was done using paired t-test. P-value < 0.05 was considered to be statistically significant.

RESULTS

In this prospective cohort study all consecutive patients who were diagnosed as pulmonary TB and pleural TB were screened during the study period in pulmonary medicine OPD, Isolation ward and DOTS clinic. A total of 153 patients were screened to obtain the sample size of 101 and after further exlusion 92 patients provided informed consent to be included of which 84 were pulmonary TB and 8 were pleural TB..

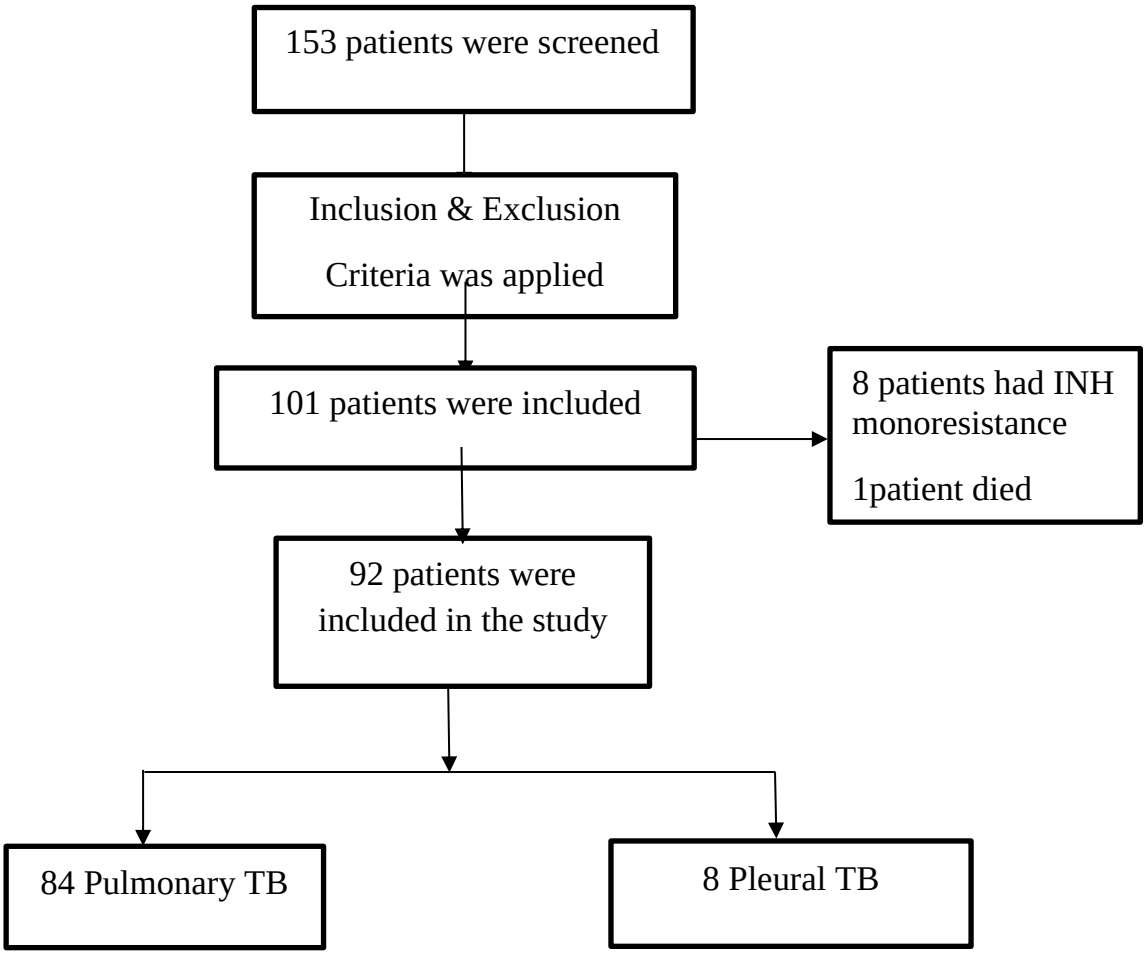

Figure 9 Strobe diagram

Baseline Characteristics:

Since there were only a small number of pleural TB patients they were excluded from analysis and shown separately. In our study we had predominance of patients in the middle age group i.e. 30-50years, with a mean age of 41years. Male were around 65%in our study. The mean BMI was 19Kg/m^2 but many of our patients were under weight. Most of our patients were non-smokers. Current smokers were 21% with mean pack years of 12.6.

VARIABLES (N=84)	TOTAL n(%) Mean±SD
AGE	
<30	23(27.38)
30-50	43(51.19)
>50	18(21.43)
MEAN AGE	40.62±13.78
SEX	
MALE	57(67.86)
FEMALE	27(32.14)
ETHNICITY(N=84)	
SOUTH INDIA	47 (55.95)
NORTH INDIA	2(2.38)
EAST INDIA	30(35.71)
WEST INDIA	0
OVERSEAS	5(5.95)
HEIGHT (cm)	163.81±9.48
WEIGHT (kg)	51.11 ±10.67
BMI (kg/m^2)	19.08± 3.54
SMOKING	
NEVER	57(66.67)
CURRENT	17(20.99)
FORMER	10(12.35)
PACK YEARS	**12.62±11.16**

Table 4 Demographic details of pulmonary TB patients

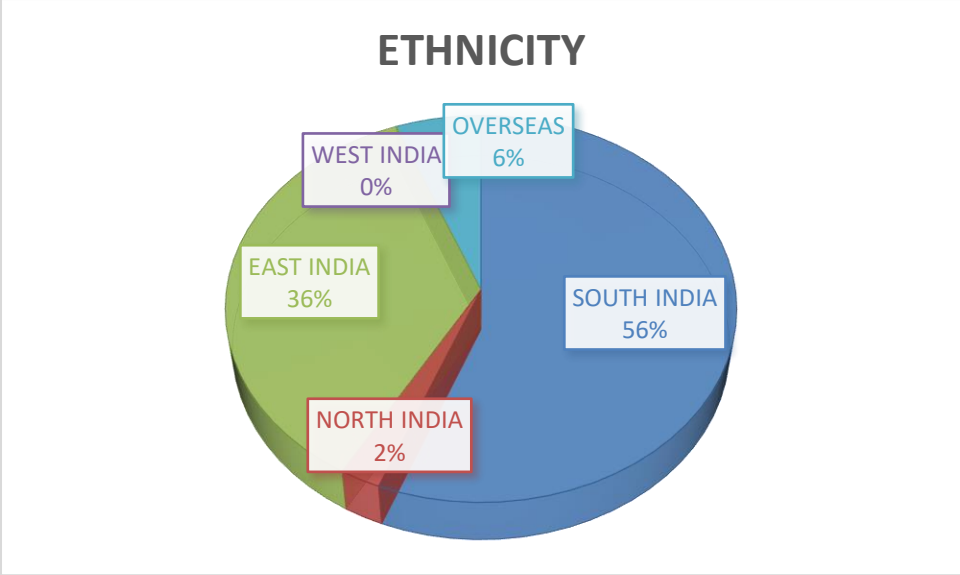

Figure 10 Ethnicity of Pulmonary TB patients

The majority of patients were from Southern part of India (56%) from Tamil Nadu followed by Andhra Pradesh. Then 36% of patients were from Eastern part of India predominantly from West Bengal. There were around 6% overseas patients from Bangladesh.

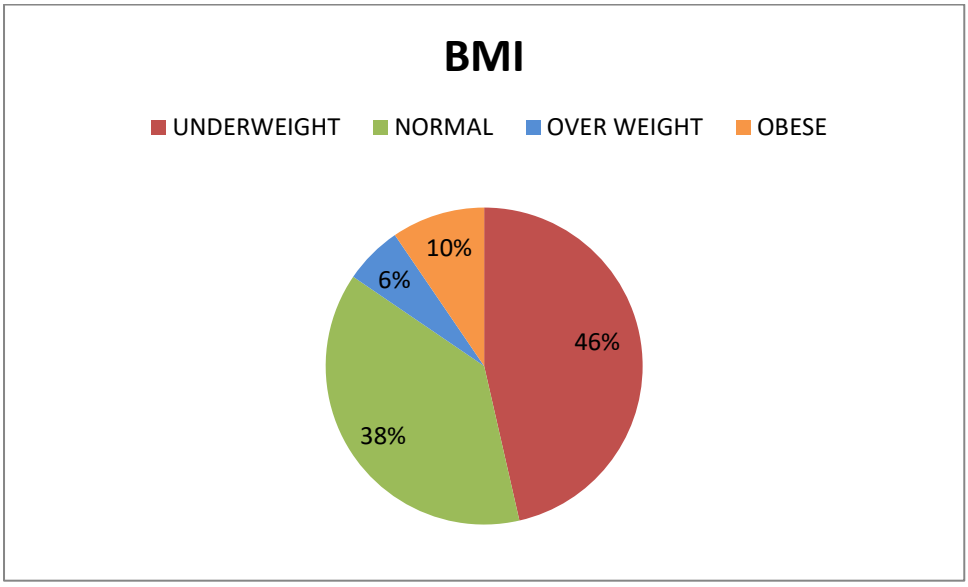

Figure 11 Distribution of BMI among pulmonary TB patients

The average BMI of the pulmonary TB patients was 19.08 (range 15.54-22.62). Classification of BMI showed that 46% patients were underweight and 38% were normal. There were 6% and 10% who were overweight and obese respectively.

Baseline symptomatology:

As per our patient profile data the distribution of symptoms varied for different patients. But Cough was the predominant symptom in most of the patients followed by loss of appetite and loss of weight.

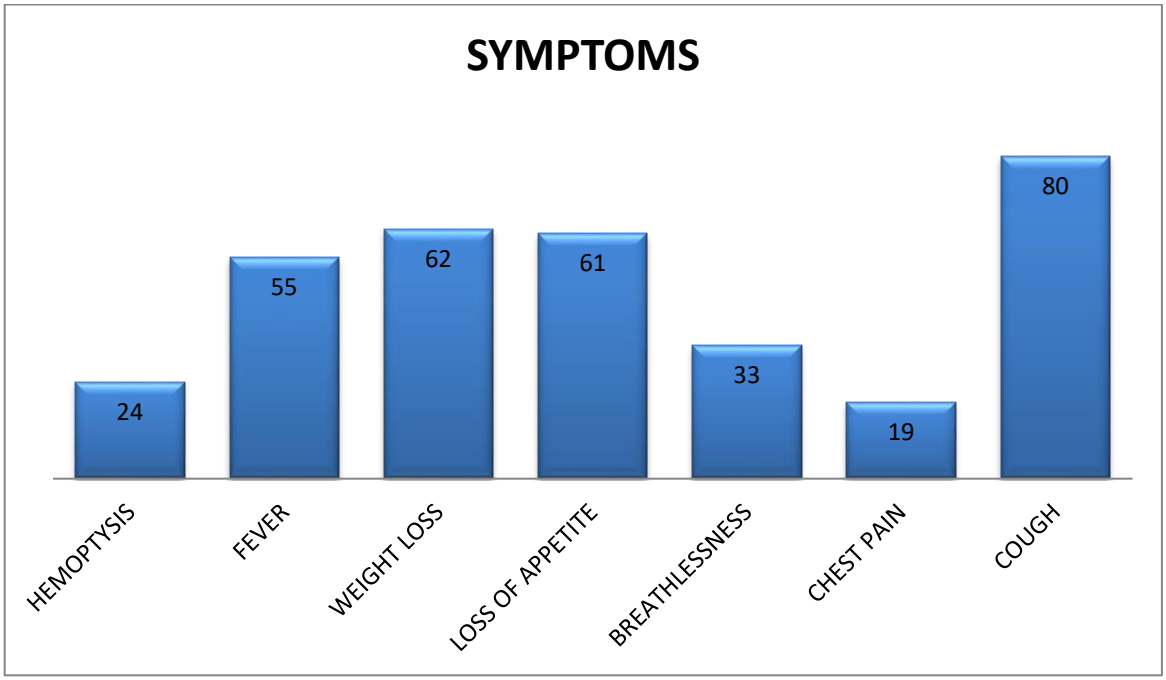

Figure 12 Symptoms at presentation

Microbiology:

The analysis of sputum smear showed 54 (64.29%) were smear positive and 30(35.71%) were smear negative. Xpert was positive in 74(88.10%), negative in 10 (11.90%) and there was no indeterminate results. Sputum culture by either LJ or MGIT grew Mycobacteria tuberculosis in 66(82.50%) of patients. Culture did not grow MTB in 14(17.50%) of patients.

VARIABLES N = 84	TOTAL n(%)
AFB SMEAR	
POSITIVE	54 (64.29)
NEGATIVE	30(35.71
XPERT	
POSITIVE	74 (88.10)
NEGATIVE	10(11.90)
LJ/MGITCULTURE	
POSITIVE	66 (82.50)
NEGATIVE	14(17.50)

Table 5 Microbiology status at baseline

The sputum smear status was scanty, 1+, 2+, 3+ in 14(25.93%), 13(24.07%), 13(24.07%) and 14(25.93%) patients respectively.

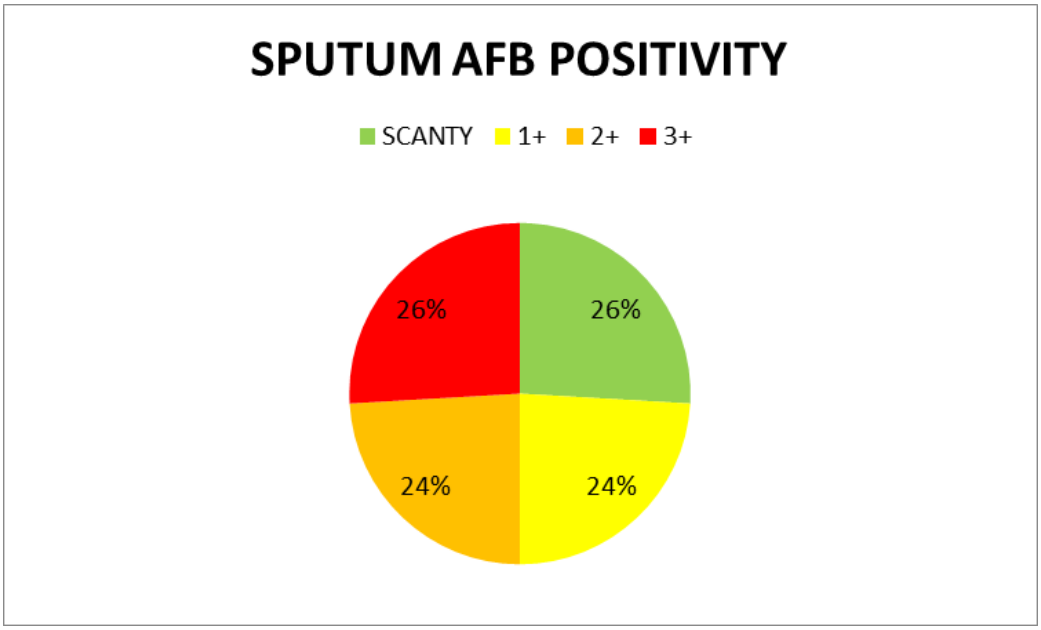

Figure 13 Severity of sputum AFB smear

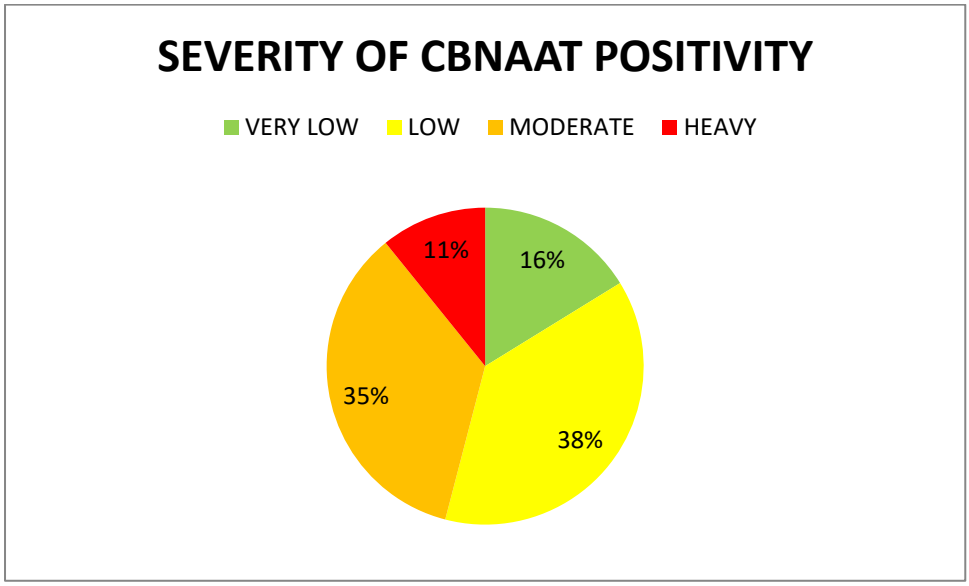

Figure 14 Severity of sputum Xpert

Analysis of sputum Xpert results and dividing into very low, low, moderate and heavy showed 12(16.22%) , 28(37.84%), 26(35.14%) and 8(10.81%) in each category respectively. Prevalence of low category was highest followed by moderate category.

SYMPTOM	2ND MONTH (N=70)(%)	6TH MONTH (N=72) (%)
COUGH IMPROVED	67 (95.71)	70(97.22)
WEIGHT GAIN	66(94.29)	68(94.44)
SPUTUMAFB POSITIVE	10(14.29)	2(2.78)

Table 6 Follow up at end of 2nd month and 6th month

As mentioned in table no 6, among those who followed up, cough improved in 95% of patients at end of intensive phase and 97% of patients at the end of treatment. Significant weight gain was present in 94% of patients at follow up. Sputum AFB smear was positive in 10(14.29%) and 2(2.78%) at the end of intensive phase and treatment completion respectively.

Risk factors:

The pulmonary TB patients were analyzed for risk factors for lung function impairment. Females had higher chance of developing abnormality which was statistically significant. Others factors like age, BMI, smoking, anaemia, diabetes, duration of cough before TB diagnosis, severity of sputum AFB smear / Xpert, culture growth were not statistically significant.

RISK FACTOR	LUNG FUNCTION IMPAIRMENT	P VALUE
Age		
<30 years	14(27.45)	
>30 years	37(72.55)	0.939
Sex		
Male	29(56.86)	
Female	22(43.14)	0.006
BMI		
Low	24(47.06)	
Normal	21(41.18)	
Obesity	6(11.76)	0.390
Smoking		
Never	35(68.63)	
Ever	16(31.37)	0.625
Anaemia	18(60.0)	0.546
Diabetes	14(48.28)	0.750
Cough		
≤ 1month	7(24.14)	
>1month	22(75.86	0.932
AFP positive		
≤1+	18(50.0)	
≥2+	18(50.0)	1.000
Xpert		
Low	19(70.37)	
Moderate	7(25.93)	
Heavy	1(3.70)	0.118
Culture positive	38(77.55)	0.085

Table 7 Risk factors for impaired lung function

Radiology:

Chest x-ray scoring was based on Percentage of lung affected, presence or absence of cavitation and the total score. Number of patients followed up was 84, 69 and 71 at baseline, 2nd month and 6th month respectively.

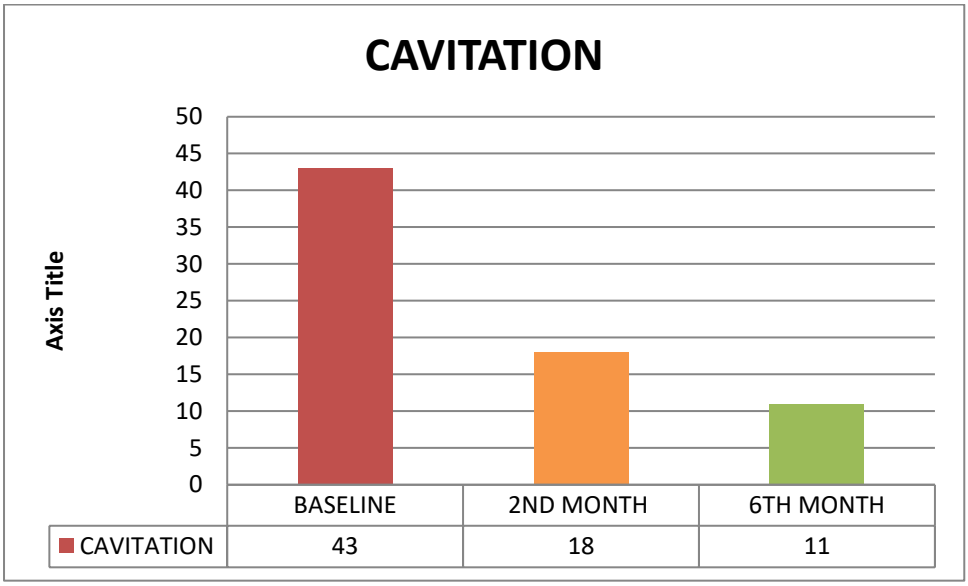

Figure 15 Cavity in chest x-ray at baseline and followup

At the time of diagnosis 43(51.9%) had cavitation in chest x-ray which reduced to 18(26.09%) at end of intensive phase and 11(15.49%) at the end of treatment completion.

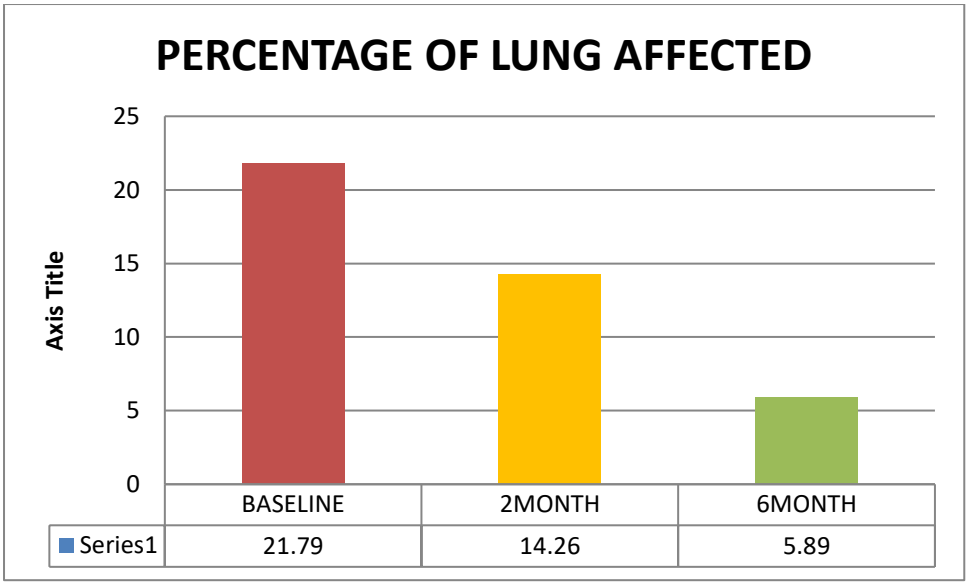

Figure 16 Percentage of lung affected at baseline and followup

The average percentage of lung affected at baseline was 21.79 which reduced to 14.26 and 5.89 at end of 2nd month and 6th month respectively.

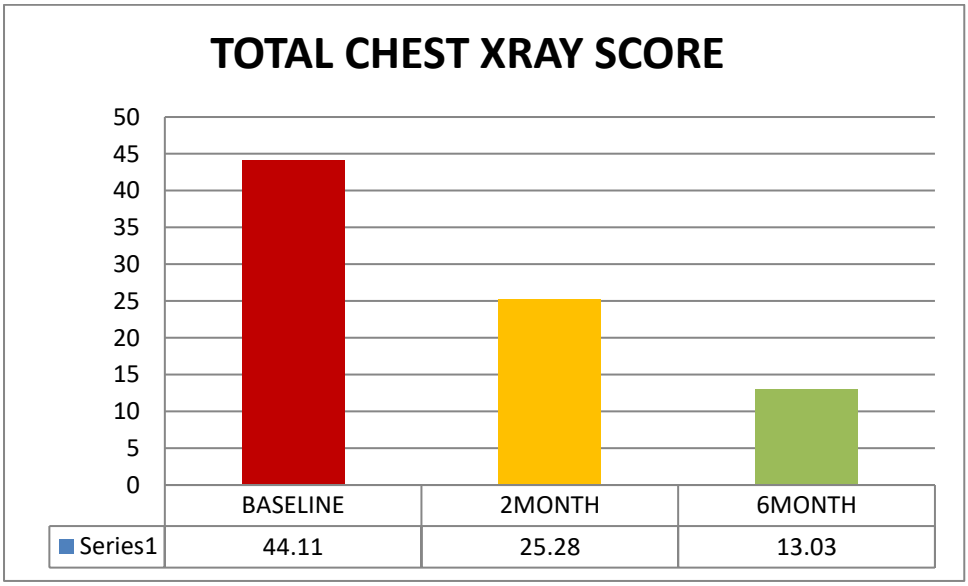

Figure 17 Total chest xray score at baseline and followup

The total chest xray score which includes cavitation and percentage of lung affected showed a mean score of 44.11 at baseline which reduced to 25.28 and 13.03 at 2nd month and 6th month respectively showing significant improvement with treatment.

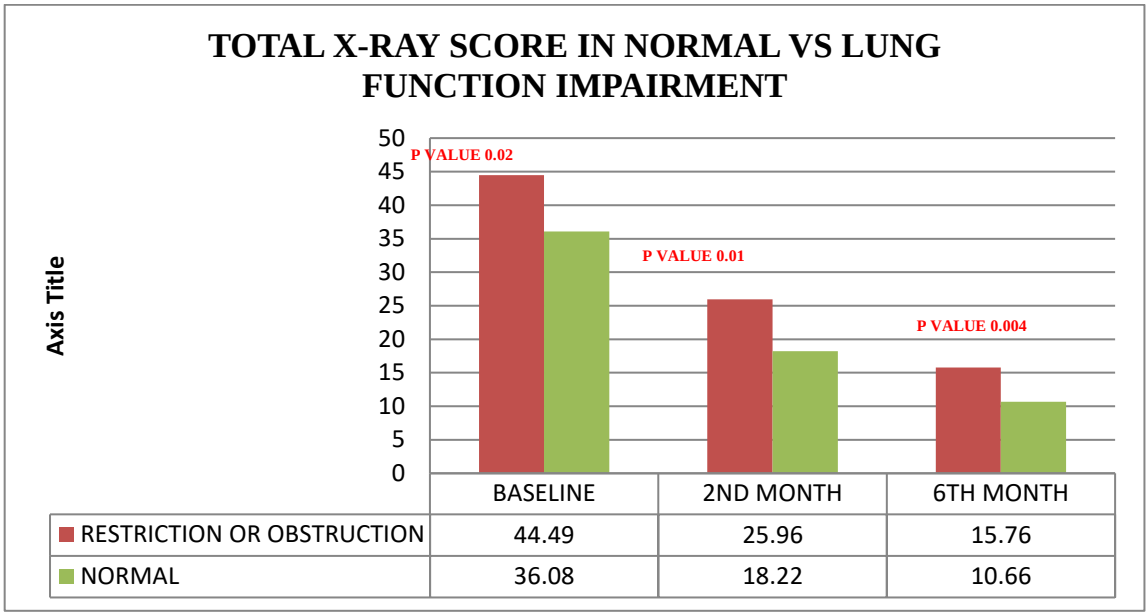

Figure 18 Total chest x-ray score in normal vs lung function impairment at baseline and follow-up

On comparing the total chest x-ray score of patients with either restrictive or obstructive ventilatory defect and patients with normal lung function showed statistically significant difference as plotted in bar diagram (fig 18) between both groups.

Spirometry:

Spirometry parameters at baseline and 2nd month and 6 th month were analysed and the trend was observed. The number of patients at baseline, 2nd month and 6th month were 81, 63 and 70 respectively. The average FEV1 at baseline was 1.98 which increased to 2.09 and 2.15 at 2nd and 6th months respectively. The average FVC at baseline was 2.33 at baseline which increased to 2.55 and 2.61 at 2nd and 6th month respectively. The trend of increase in spirometry parameters is plotted in the line diagram below.

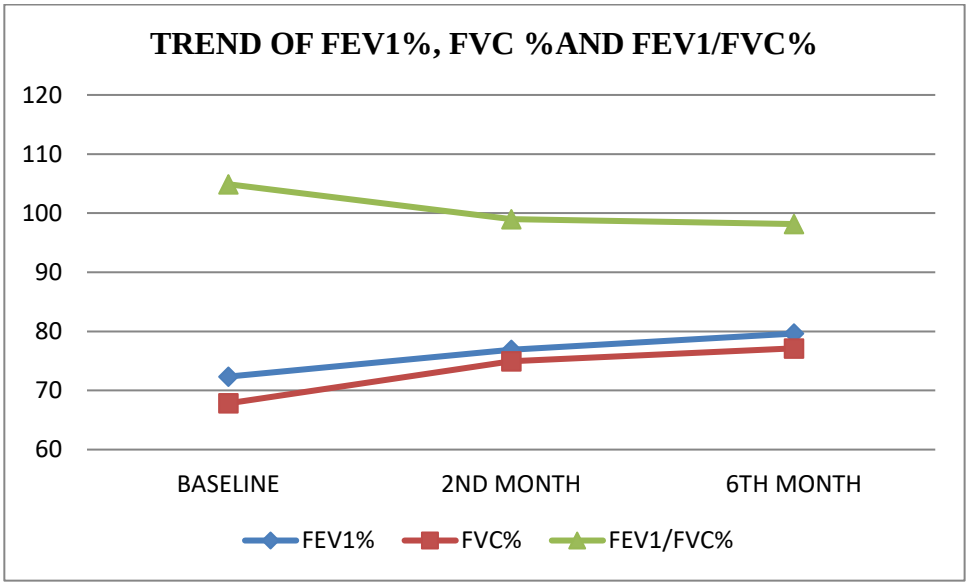

Figure 19 Change in FEV1%, FVC% and FEV1/FVC% at baseline and follw-up

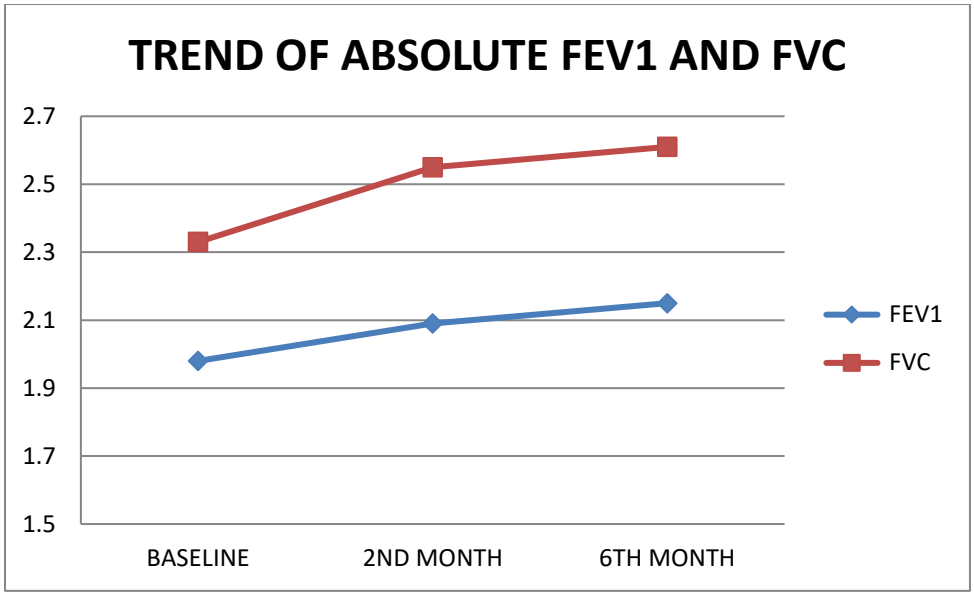

Figure 20 Trends of absolute value of FEV1 and FVC

VARIABLE (POST BD)	BASELINE (81) mean ±SD	2ND MONTH(63) mean±SD	6TH MONTH(70) mean±SD
FEV1	1.98 ±0.77	2.09±0.70	2.15±0.71
FEV1%	72.35±19.60	76.90±15.98	79.63±15.43
FVC	2.33±0.83	2.55±0.76	2.61±0.77
FVC %	67.83±17.60	74.34±13.56	77.13±13.89
FEV1/FVC	84.68±10.36	77.39±22.46	80.09±16.88
FEV1/FVC%	104.89±12.93	99.01±11.15	98.16±11.48

Table 8 Spirometry parameters at baseline and follow-up

Diagnosis of Lung function Impairment:

Based on spirometry, patients were classified as normal, obstructive ventilatory defect, restrictive ventilatory defect or any abnormality (obstruction+ restriction). Number of patients analyzed was 81, 63 and 70 at baseline, 2nd month and 6th month respectively. Obstruction was found to be about 8 to 9% during all three visits. Restriction at baseline was 54% which reduced to 44% at end of treatment completion. Either obstruction or restriction was found in 62% at the time of diagnosis and 52% at the end of treatment.

FOLLOWUP	OBSTRUCTION n(%)	RESTRICTION n(%)	ANY ABNORMALITY n(%)	NORMAL n(%)
BASELINE(n=81)	7(8.6)	44(54.32)	51(62.96)	30(37.04)
2ND MONTH(n=6)	5(8.06)	33(53.22)	38(61.29)	24(38.7)
6TH MONTH(n=70)	6(8.57)	31(44.28)	37(52.8)	33(47.1)

Table 9 Interpretation of Spirometry

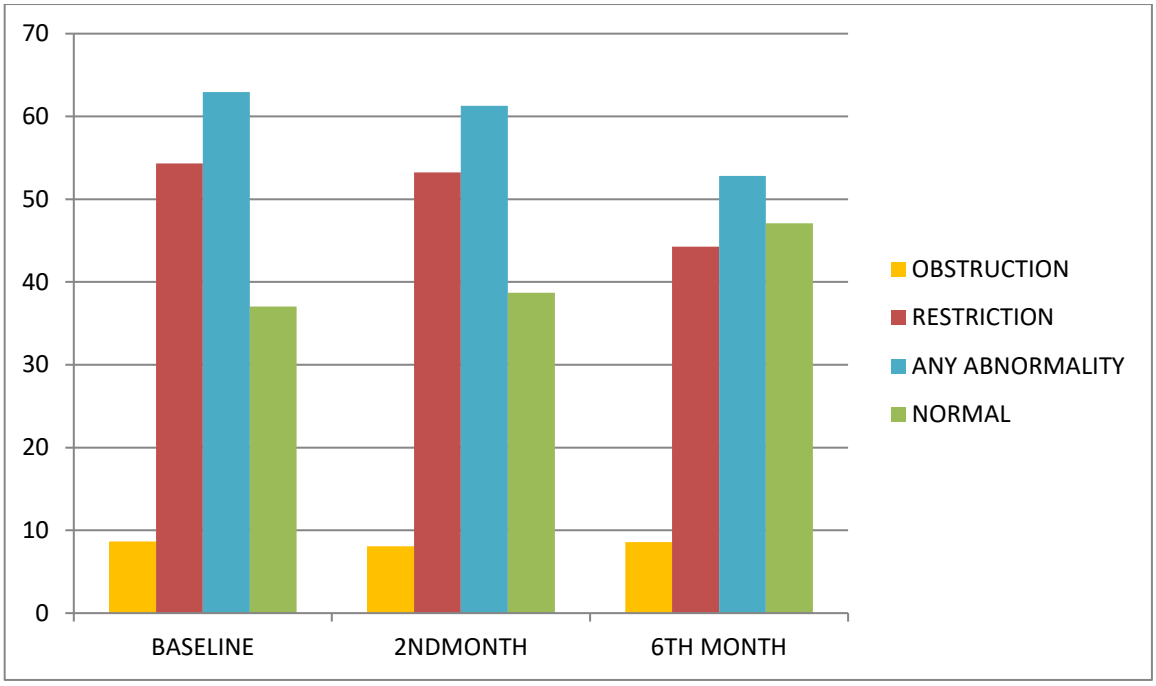

Figure 21 Prevalence of lung function impairment

Severity of Lung function abnormality:

At baseline out of 44 patients who had restriction, 15 were mild, 22 were moderate and 7 were severe. At 2nd month followup at the time of completion of intensive phase of ATT out of 33 who had restriction 18 were mild, 13 was moderate and 2 were severe showing decrease in severity. At 6th month while completing treatment out of 31 who had restriction16 had mild, 14 had moderate and 1 had severe disease.

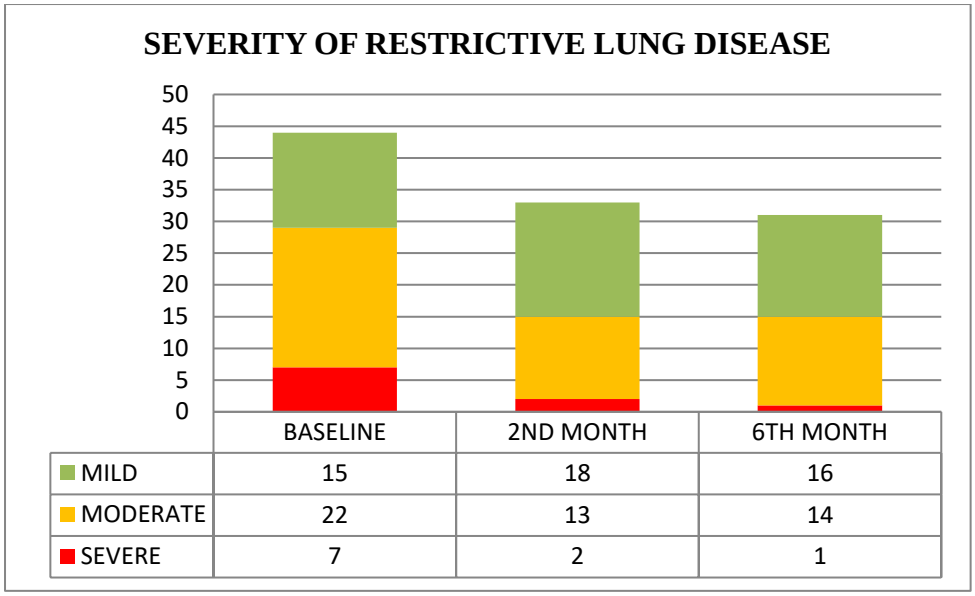

Figure 22 Trend of severity of restrictive pathology at baseline and followup

At baseline out of 7 patients who had obstruction, 3 were moderate and 4 were severe. At 2nd month followup at the time of completion of intensive phase out of 5 who had obstruction 3 was moderate and 2 were severe. At 6th month while completing treatment out of 6 who had obstruction, 3 had moderate and severe disease each.

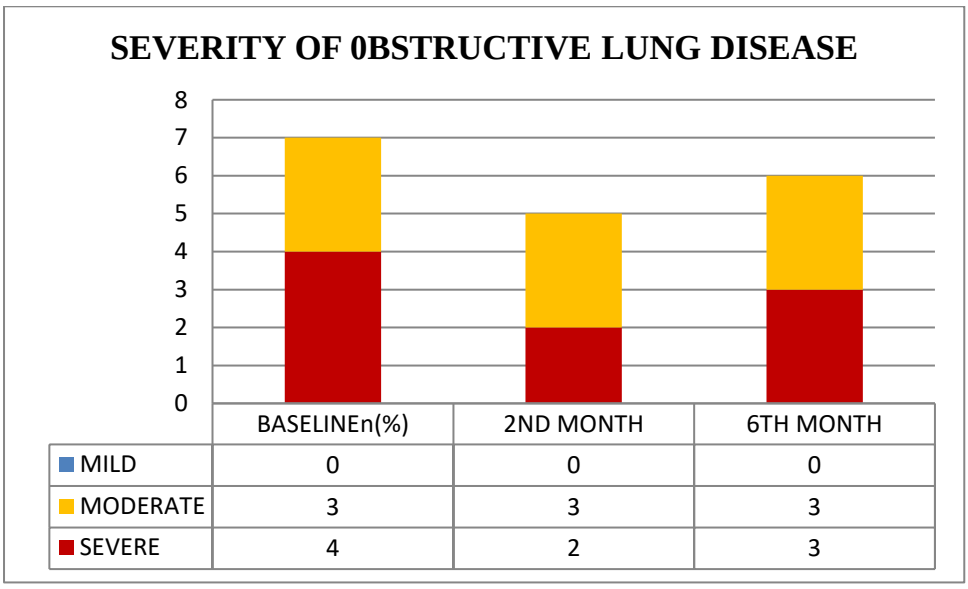

Figure 23 Trend of Severity of obstructive pathology at baseline and followup

VARIABLE	BASELINE TO 2ND MONTH N=60	P VALUE	BASELINE TO 6th MONTH N=67	P VALUE
FVC	0.19±0.75	0.002	0.265±0.394	<0.001
FVC%	5.88±11.78	0.003	8.31±12.84	<0.001
FEV1	0.07±0.26	0.02	0.144±0.258	<0.001
FEV1%	3.36±10.36	0.014	5.76±10.56	<0.001
FEV1/FVC	2.38±8.65	0.03	5.08±15.64	0.009
FEV1/FVC%	6.65±10.83	0.001	7.51±12.78	<0.001

Table 10 Improvement in lung function

Static lung function:

At 2nd month and 6th month after smear conversion diffusion lung capacity for carbon monoxide (DLCOc) and total lung capacity (TLC) were measured. The mean absolute DLCOc value at 2nd month followup was 7.15 which increased to 7.22 at treatment completion. The mean absolute TLC was 3.77 at 2nd month which increased to 4.46 at treatment completion.

STATIC LUNG FUNCTION	2ND MONTH N=67 mean±SD	6TH MONTH N=71 mean±SD
DLCOc	7.15±2.40	7.22±2.45
DLCOc(pre/pred)	85.99±28.83	87.49±3.57
TLC	3.77±0.94	4.46±4.87
TLC(pre/pred)	74.16±13.76	78.48±14.36

Table 11 Static pulmonary function test

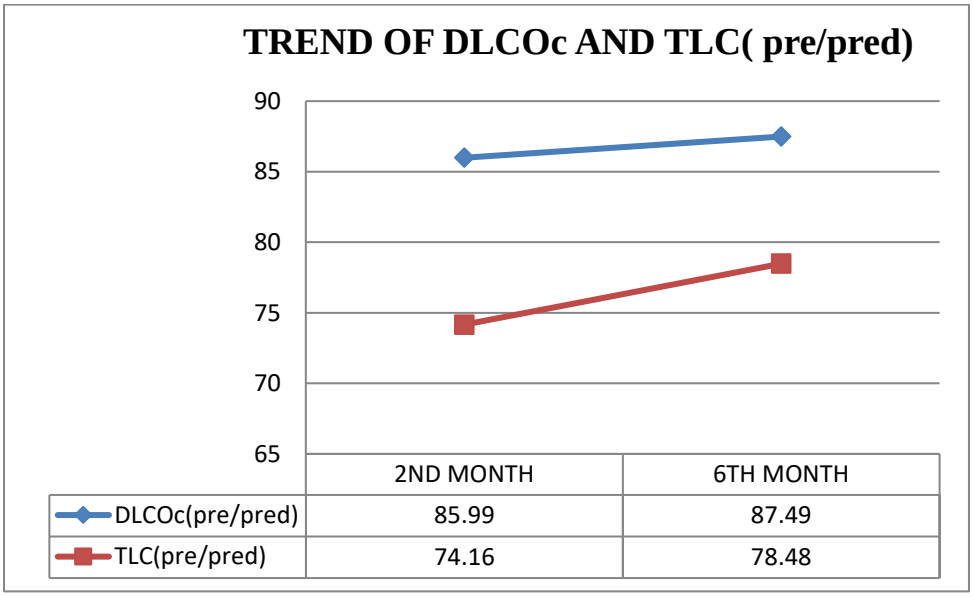

Figure 24 Trend of change in DLCOc and TLC (pre/pred) during followup

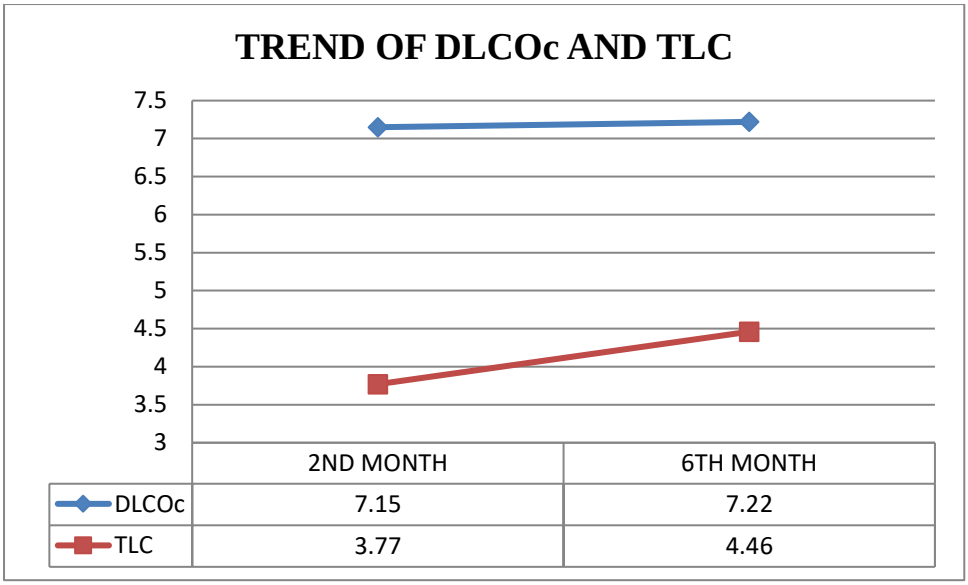

Figure 25 Trend of change in absolute DLCOc and TLC during followup

The fig no 25 and table no 12 indicates the change in static lung function from 2nd month to 6th month. The line plot shows significant upward trend in TLC, however the DLCOc does not show significant change.

VARIABLE	CHANGE FROM 2ND TO 6TH MONTH N=71	P VALUE
DLCOc	0.078±0.70	0.38
DLCOc(pre/pred)	1.49±16.94	0.49
TLC	0.76±5.07	0.23
TLC (pre/pred)	4.31±15.54	0.03

Table 12 Change in DLCOc and TLC during followup

The average change in DLCOc (pre/pred) from 2nd month to 6th month was 1.49 which was not statistically significant. But the change in TLC (pre/pred) is 4.31with a P value of 0.03 which is statistically significant. This table shows that there is significant improvement in lung capacity with treatment.

	RESTRICTION BY FVC	RESTRICTION BY TLC	DIFFERENCE
2ND MONTH	33	29	4
6TH MONTH	31	26	5

Table 13 Restriction by FVC and TLC

Those who were diagnosed to have restriction based on FVC were subjected to TLC to identify true restriction. In the 2nd month and 6th month 4 and 5 patients respectively were over diagnosed to have restriction based on FVC alone.

SGRQ Quality of life score:

The analysis of data on quality of life at baseline, end of intensive phase and end of treatment showed significant improvement with ATT. The symptom domain had the highest score followed by activity domain. Impact domain was the least affected. The average total score at baseline was 41 which decreased to 22 at 2nd month and 13 at end of treatment. However even after completing treatment there was still residual impairment in quality of life score in all 3 domains.

INDICATORS	VISITS	MEAN
SYMPTOMS	BASELINE	49.65±14.48
	2ND MONTH	28.86±10.74
	6TH MONTH	18.09±8.97
ACTIVITY	BASELINE	38.37±23.82
	2ND MONTH	21.17±18.18
	6TH MONTH	12.94±11.29
IMPACT	BASELINE	37.80±17.77
	2ND MONTH	19.48±12.68
	6TH MONTH	10.42±7.54
TOTAL SCORE	BASELINE(N=84)	41.45±16.92
	2ND MONTH(N=67)	22.74±12.25
	6TH MONTH (N=71)	13.34±7.65

Table 14 SGRQ score at baseline and followup

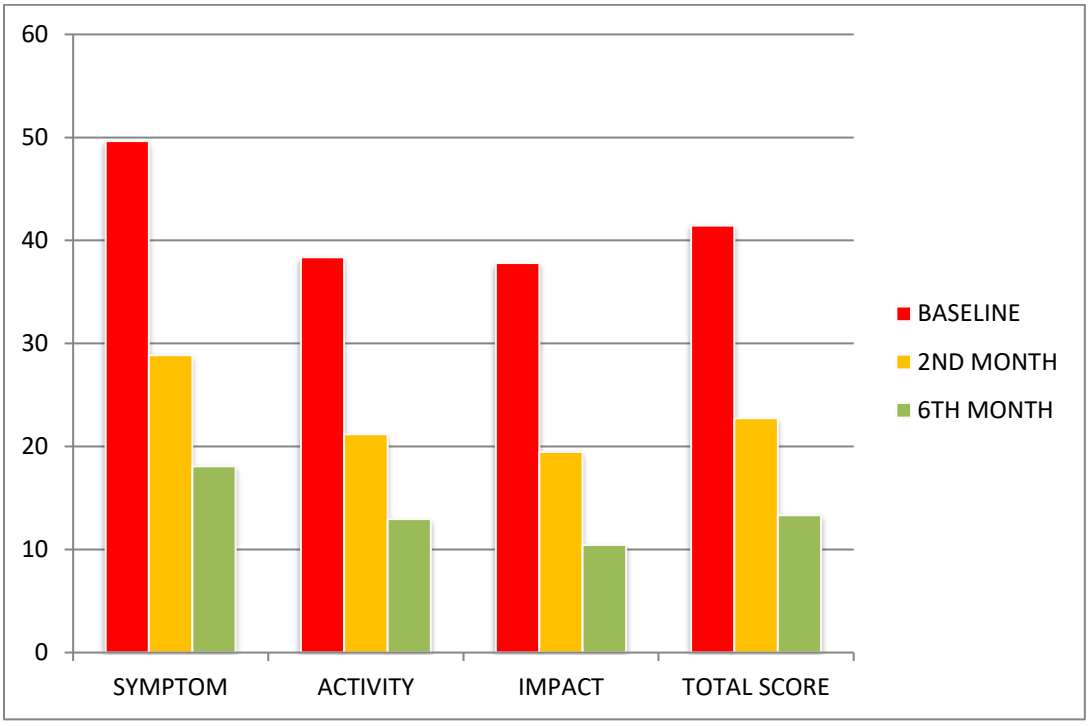

Figure 26 Change in SGRQ score from baseline to treatment completion

Quality of life and lung function impairment:

On comparing the total SGRQ score in patients with normal lung function and any lung function impairment (obstruction+ restriction) there was statistical significance at baseline, 2nd month and 6th month with p value of 0.02, 0.01 and 0.004 respectively.

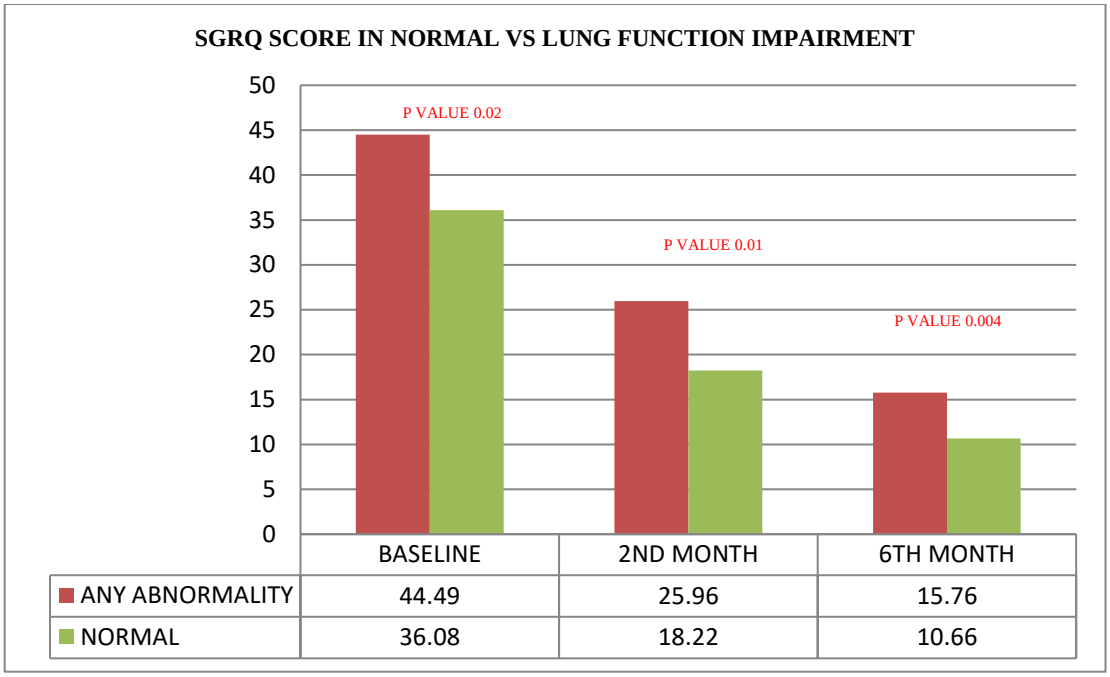

Figure 27 SGRQ score in normal vs lung function impairment at baseline and followup

.**Pleural TB:**

As the sample size of pleural TB patients was low they were not included in analysis. The pleural fluid analysis showed lymphocytic effusion in 7 patients which was exudative in all 8 patients. One patient was diagnosed based on pleural fluid Xpert positivity and culture was also positive at 2 months. Remaining 7 patients had negative pleural fluid Xpert and ADA was inconclusive and underwent pleural biopsy. Pleural biopsy tissue was Xpert positive in 3 out of 7 patients and culture grew in 5 out of 7 patients. Biopsy of these 7 patients showed granulomatous inflammation.

PLEURAL TB	n(%)
PLEURAL FLUID ANALYSIS(n=8)	
EXUDATIVE EFFUSION	8(100)
LYMPHOCYTIC	7(87.5)
NEUTOPHILC	1(12.5)
CBNAAT POSITIVE	1(12.5)
MGIT/CULTURE GROWTH	1(12.5)
PLEURAL BIOPSY (n=7)	
XPERT POSITIVITY	3(42.8)
MGIT/LJ CULTURE GROWTH	
GROWN	5(71.42)
NO GROWTH	2(28.50)
BIOPSY	
GRANULOMATOUS INFLAMMATION	7(100)

Table 15 Microbiology in pleural TB patients

VARIABLE (POST BD)	BASELINE (8) mean ±SD	2ND MONTH(8) mean±SD	6TH MONTH(8) mean±SD
FEV1	1.88±.49	2.19±0.53	2.27±0.55
FEV1%	63.05±9.34	74.54±16.08	76.67±15.69
FVC	2.14±0.64	2.48±0.61	2.61±0.57
FVC %	59.23±10.83	69.72±14.86	73.11±12.63
FEV1/FVC	89.99±4.76	88.93±6.60	87.53±7.62
FEV1/FVC%	103.42±7.31	102.49±8.39	100.80±9.26
DLCOc	-	90.8±14.96	91.05±4.27
TOTAL LUNG CAPACITY	-	73.68±14.88	75.26±12.87

Table 16 Lung function in pleural TB patients

All 8 patients had restrictive ventilatory defect of which 2 of them normalized at the end of treatment and remaining 6 of them continued to have persistent restriction. As shown in table 16 there was significant improvement in FVC following treatment.

	OBSTRUCTION n(%)	RESTRICTION n(%)	NORMAL n(%)
BASELINE	0	8(100)	0
2ND MONTH	0	6(75)	2 (25)
6TH MONTH	0	6(75)	2 (25)

Table 17 Lung function impairment in pleural TB patients

DISCUSSION:

As per our knowledge this study is first of its kind to observe the change in lung function through the course of TB disease. Lung function test was done at the start of treatment and end of intensive phase after smear conversion and at the end of continuation phase and the trend of lung function change was observed. We observed the individuals developing persistent lung function impairment at treatment completion in spite of microbiological cure.

In most of the available literature spirometry is performed after completing treatment or after smear conversion. Very little data is available on the lung function before initiating treatment for TB and the trend of lung function change with treatment. Many studies reported a higher incidence of airway obstruction than restriction (51). Association between COPD and TB was proven by many studies like BOLD, PLATINO (61) (63) . Some studies have reported restrictive ventilator defect to be the predominant defect (75) (74).

As mentioned in the strobe diagram, the patients satisfying the inclusion criteria were included to reach a final required sample size. Sample size was calculated based on a similar study, the details of which are mentioned under Methodology.

Most of our patients belonged to the middle age group (30 to 50). Meta-analysis by Horton et al and many other studies quote male predominance in middle and lower socioeconomic countries , however the reason is unclear (83) (84). In our study population also majority were male. Low BMI is a known risk factor for the development of TB and our study also had more individuals who were underweight according to Asia Pacific WHO classification of BMI (17) (79).

The diagnostic yield of sputum Xpert was about 90% and sputum MTB culture was about 85% which is comparable to the WHO report (45). Risk factors which can be associated with the development of lung function impairment in TB were assessed. Only female sex correlated with higher probability of development of lung function impairment (p value – 0.006), which can be explained by the physiologically lower lung function in females. Other risk factors like malnutrition, anaemia, diabetes, severity of sputum AFB smear or Xpert did not show significant probability of developing impaired lung function.

Chest x-ray interpretation was done based on RePORT consortium protocol. There was significant proportion of the individuals with cavitary lung lesions at the time of diagnosis (51%) which significantly reduced but persisted after treatment in about 15% of individuals. Cavitation is considered to be one of the causes for the development of airflow obstruction (53).

However we did not identify any relation between cavitation and development of airflow obstruction which could be because of lower incidence of obstruction in our study. The total chest-xray score correlated with lung function the presence of lung function defect (p value – 0.004).

Spirometry done at baseline before initiating therapy identified 51(63%) patients to have lung function defect and 30(37%) to be normal. On classifying the lung function impairment restrictive ventilatory defect was noted in in 44 patients (54%) and 7 patients (9%) had airflow obstruction. According to literature both restrictive and obstructive defects occur in varying degrees. Akkara et al reported about 86% prevalence of obstructive defect in patients treated for TB(51). Nair et al, Rekha et al and Gupte et al reported predominant restrictive defect (75) (74) (66). The trend of FEV1, FVC and FEV1/FVC during the course of illness showed that predominant improvement happens between treatment initiation and 2 months, which corresponds to the known fact that most of the radiological and microbiological improvement happens by 2 months. The change in the same parameters from baseline to 2nd month and baseline to treatment completion shows statistically significant improvement.

After sputum smear conversion at the end of 2 months and end of treatment static lung function was performed. There was statistically significant improvement in total lung capacity with a p value of 0.03. Diffusion lung capacity for carbon monoxide showed mild improvement which was not

statistically significant. However it is not known if the improvement in DLCO happens during initial 2 months since it could not be measured at baseline due to risk of TB transmission. DLCO is decreased in TB patients due to decrease in area available for ventilation (53) (85). However there is not much evidence of effect of TB on DLCO and the trend of change in DLCO.

SGRQ questionnaire has been validated for measurement of health related quality of life assessment in Tuberculosis patients by Pasipanodya et al (73). They found a mean difference of 13.5 in total score between post TB patients and those with Latent TB. According to the different studies in a normal individual the symptom, activity, impact and total score is about 12, 9,2 and 6 respectively. In our study at the time of treatment completion the mean symptom, activity and total score were 18.09, 12.94, 10.42 and 13.34 respectively. Those with lung function impairment showed a higher total score compared to normal lung function which was statistically significant (p value - 0.04). Similar to other studies our study also showed lower impact score compared to symptom and activity score (75) (74) (86). It is evident that despite microbiological cure the quality of life is affected post treatment which could result in continued morbidity. Due to technical difficulties pleural TB patient sample size was low hence not analyzed separately.

Limitation:

There were few limitations in this study. As fixed cut of values rather than lower limit of normal was used to classify ventilatory defects and hence there is a possibility of measurement bias. As our hospital is a tertiary center, study participants were form all over the country and overseas which made follow-up visits difficult which could have led to transfer bias. However it was considered that those who were lost to followup and those retained in the study are fundamentally same. While compared to other similar studies the incidence of obstructive lung disease was significantly low in our study. Although the sample size was calculated based on a similar study that was done, the sample size of 92 appears to be seemingly small to and may need to higher number to obtain statistically sound results. Pleural TB patients could not perform spirometry at baseline visits due to technical difficulties. Hence further studies are needed to assess the lung function in pleural TB patients.

Conclusion:

In our study we conclude that there is significant impairment in lung function in pulmonary TB patients which persist despite microbiological cure. There is improvement in spirometry parameters like FEV1, FVC and FEV1/FVC with treatment which is statistically significant. Significant improvement happens in the initial two months. The predominant defect is

restriction at the time of diagnosis (54%) and after completing treatment (44%). Unlike the popular hypothesis our study showed lower incidence of obstructive defect (9%). DLCO was reduced but did not show statistically significant improvement with treatment. However DLCO improvement was assessed only from 2nd month to treatment completion so there is no data on change in the first 2 months. Total lung capacity increased from 2nd month to end of treatment which was statistically significant. Using FVC alone over diagnosed restriction in few patients, hence its ideal to do TLC to identify true restriction. Total chest x-ray score showed improving trend with treatment which was statistically significant while comparing with lung function. Quality of life assessed by SGRQ score also showed significant improvement with treatment in symptom, activity, impact and total score. There was statistically significant association between total score and lung function impairment. This is the first study which has looked at the trend of lung function change during the course of illness. Further studies with larger sample size are required to confirm the trend of lung function and the prevalence of different ventilatory disorders in pulmonary TB patients. In view of higher incidence of lung function impairment despite microbiological cure serial lung function monitoring is needed in patients who are both symptomatic and asymptomatic for early diagnosis and to reduce morbidity and mortality.

Future direction:

The change in lung function during the course of TB disease is not well understood. Understanding the natural trend in change of lung function in TB patients with treatment will help in early diagnosis and treatment of those who will develop residual impairment. Biomarker studies could attempt to predict those who undergo lung damage. Further studies are needed to confirm the findings of this study. Further studies should followup patients beyond to see if lung function continued to improve. Lung function assessment should be considered as a part of national TB program at least at the end of treatment to document residual lung damage and predict future morbidity and mortality.

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Annexure 1: IRB Approval Page 1

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

July 14, 2018

Dr. Dhivya Roy A,
PG Registrar,
Department of Pulmonary Medicine ,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant: New Proposal:**
The effect of Appropriate Att on Recovery of Pulmonary and Pleural Tuberculosis and the impact of tuberculosis on lung function and quality of life in newly Diagnosed Patients.
Dhivya Roy A, Employment Number: 21466, PG Registrar/ Pulmonary Medicine, Dr.D.J. Christopher, Employment Number: 14193, Pulmonary Medicine, Dr.Balamugesh T, Employment Number – 31292, Professor and Head, Department of Pulmonary Medicine, Dr. Richa Gupta, Employment number – 31330, Pulmonary Medicine.

Ref: IRB Min. No. 11153 [OBSERVE] dated 06.02.2018

Dear Dr. Dhivya Roy A,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. D J Christopher, Dept. of Pulmonary Medicine, CMC, Vellore

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
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Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

July 14, 2018

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Ref: IRB Min. No. 11153 [OBSERVE] dated 06.02.2018

Dear Dr. Dhivya Roy A,

The Institutional Review Board (**Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "The effect of Appropriate Att on Recovery of Pulmonary and Pleural Tuberculosis and the impact of tuberculosis on lung function and quality of life in newly Diagnosed Patients" on February 06th 2018.

The Committee reviewed the following documents:

1. IRB application format
2. Case Report Form
3. Chest X-ray Guidelines
4. Patient Information Sheet and Consent form (Tamil, English, Hindi, Bengali)
5. Cv's of Drs. D J Christopher, Richa M, Balamugesh, Dhivya, Tunny M.
6. No. of documents 1- 5.

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on February 06th 2018 in the Jacob Chandy Hall, Paul brand Building, Christian Medical College, Vellore 632 004.

2 of 4

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore .	Internal, Clinician
Dr. Anna B. Pulimood	MBBS, MD, PhD	Principal, Chairperson-Research Committee, IRB, CMC, Vellore	Internal, Clinician
Dr. Thomas V Paul	MBBS, MD, DNB, PhD	Professor, Endocrinology, CMC, Vellore	Internal, Clinician
Dr. RekhaPai	BSc, MSc, PhD	Associate Professor, Pathology, CMC, Vellore	Internal, Basic Medical Scientist
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist &Epidemiologist
Ms. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Vivek Mathew	MD (Gen. Med.) DM (Neuro) Dip. NB (Neuro)	Professor, Neurology, CMC, Vellore	Internal, Clinician
Dr. Inian Samarasam	MS, FRCS, FRACS	Professor, Surgery, CMC, Vellore	Internal, Clinician
Dr. Asha Solomon	MSc Nursing	Associate Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Sowmya Sathyendra	MBBS, MD (Gen. Medicine)	Professor, Medicine III, CMC, Vellore	Internal, Clinician
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Mrs. Sheela Durai	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. John Antony Jude Prakash	MBBS, MD	Professor, Clinical Microbiology, CMC, Vellore.	Internal, Clinician.

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "The effect of Appropriate Att on Recovery of Pulmonary and Pleural Tuberculosis and the impact of tuberculosis on lung function and quality of life in newly Diagnosed Patients" on a monthly basis.Please send copies of this to the Research Office(research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 1,00,000/- INR (Rupees One Lakh Only) will be granted for 2 years. 50,000/- INR (Rupees Fifty Thousand only) will be granted for 12 months as an Ist Installment. The rest of the 50,000/- INR (Rupees Fifty thousand only) will be released at the end of the first year as 2 nd Installment.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.,
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min. No. 11153 [OBSERVE] dated 06.02.2018 4 of 4

Annexure 2: consent forms

Format for Informed Consent Form for Subjects

INFORMED CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title: THE EFFECT OF APPROPRIATE ATT ON RECOVERY OF PULMONARY AND PLEURAL TUBERCULOSIS AND THE IMPACT OF TUBERCULOSIS ON LUNG FUNCTION AND QUALITY OF LIFE IN NEWLY DIAGNOSED PATIENTS

Study Number: _____

Subject's Initials: _____
Subject's Name:_____ Date of Birth / Age: _____

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

(iii) I understand that the lead investigator , the Ethics Committee and the regulatory authorities

will not need my permission to look at my health records both in respect of the current study and any

further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this

access. However, I understand that my identity will not be revealed in any information released to third parties or published.

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).

(v) I agree to take part in the above study.

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____ Signature:

or

Representative: _____
Date: _____/_____/_____
Signatory's Name: _____

Signature of the Investigator: _____ Date:
_____/_____/_____
Study Investigator's Name: _____

Signature or thumb impression of the Witness:
_____ Date: _____/_____/_____
Name & Address of the Witness: _____

ஆய்வுப் படிப்பில் பங்கேற்பதற்கான படிவம்

ஆய்வுக்கான தலைப்பு: நுரையீரலில் புதிதாக காசநோய் கண்டறியப்பட்ட நோயாளியின் நுரையீரலில் மருந்துகள் காரணமாக ஏற்படும் மாற்றங்கள் மற்றும் நுரையீரல் செயல்பாடுகள் மற்றும் வாழ்க்கை தரத்தில் ஏற்படும் மாற்றங்கள்.

எண்: _____

தொடக்கங்கள்: _____

பெயர்: _____

பிறந்த தேதி / வயது: _____

(i) மேற்கூறிய ஆய்வுக்காக _____ தேதியிட்ட தகவல் தாளை நான் படித்து புரிந்து கொண்டேன் என்பதை உறுதிப்படுத்துகிறேன் மற்றும் படிப்பைப் பற்றி கேள்விகளைக் கேட்பதற்கான வாய்ப்பு இருந்தது. [ ]

(ii) ஆய்வில் எனது பங்களிப்பு தன்னார்வமாக உள்ளது என்பதையும் நான் எந்த நேரத்திலும் இந்த மருத்துவப் பாதுகாப்பு அல்லது சட்ட உரிமைகள் பாதிக்கப்படாமல், எந்தவொரு காரணமும் இல்லாமல் இந்த ஆய்வில் இருந்து விலகி விடுவதற்கு எனக்கு சுதந்திரம் உண்டு என்பதை புரிந்துகொள்கிறேன். [ ]

(iii) இந்த ஆய்வின் நோக்கம் மற்றும் அதனுடன் தொடர்புடைய எந்தவொரு ஆராய்ச்சிக்காகவும் எனது சுகாதார பதிவேடுகளை ஆராயும் முன்னணி புலனாய்வாளர்கள், ஒழுக்கவியல் குழு மற்றும் ஒழுங்குமுறை அதிகாரிகளுக்கு எனது அனுமதி தேவையில்லை என்று புரிந்து கொள்கிறேன். நான் பின்வாங்கினாலும் இது உண்மை என்று உணர்கிறேன். இருப்பினும், மூன்றாம் தரப்பினருக்கு வெளியிடப்பட்ட தகவல்கள் அல்லது கட்டுரைகளில் வெளியிடப்பட்ட தகவல்களில் எனது பெயர் வெளியிடப்படாது என்பதை நான் புரிந்து கொள்கிறேன். [ ]

(iv) விஞ்ஞான நோக்கம் (கள்) பயன்படுத்தப்பட்டு வரும் இந்த ஆய்விலிருந்து எழும் எந்தவொரு தரவு அல்லது முடிவுகளின் பயன்பாட்டை நான் கட்டுப்படுத்த மாட்டேன் என்று ஒப்புக்கொள்கிறேன். [ ]

(v) மேலே உள்ள படிப்பில் பங்கேற்க நான் ஒப்புக்கொள்கிறேன். [ ]

சட்டபூர்வமாக ஏற்றுக்கொள்ளப்பட்ட கையொப்பம் (அல்லது கை முத்திரை)

தேதி: _____ / _____ / _____

கையொப்பமிட்ட பெயர்: _____ கையொப்பம்:

அல்லது

பிரதிநிதி: _____

தேதி: _____ / _____ / _____

கையொப்பமிட்ட பெயர்: _____

ஆராய்ச்சியாளரின் கையொப்பம்: _____

தேதி: _____ / _____ / _____

ஆய்வு ஆராய்ச்சியாளரின் பெயர்: _____

சாட்சியின் கையொப்பம் அல்லது கை எண்ணம்: _____

தேதி: _____ / _____ / _____

சாட்சியின் பெயர் மற்றும் முகவரி: _____

अध्ययन अध्ययन में भागीदारी के लिए फॉर्म

अध्ययन का शीर्षक: फुफ्फुसीय मरीजों के फेफड़े में फेफड़ों में फेफड़े और फेफड़े के कार्यों और जीवन शैली में परिवर्तन में परिवर्तन।

संख्या: _____

शुरुआत: _____

नाम: _____

जन्म तिथि / आयु की तारीख: _____

(i) मैं पुष्टि करता हूं कि मैंने उपरोक्त विश्लेषण के लिए _____ के सूचना पत्र को पढ़ और समझ लिया है और अध्ययन के बारे में सवाल पूछने का अवसर मिला है। []

(ii) मैं समझता हूं कि अध्ययन में मेरा योगदान स्वैच्छिक है और मैं समझता हूं कि बिना किसी कारण के इस अध्ययन से बिना किसी चिकित्सा देखभाल या कानूनी अधिकारों को छोड़ने की मेरी आजादी है। []

(iii) मैं समझता हूं कि इस अध्ययन का उद्देश्य और उसके साथ जुड़े किसी भी शोध प्रमुख जांचकर्ताओं, नैतिकता दल और नियामक प्राधिकरणों के लिए मेरे स्वास्थ्य अभिलेखों की जांच करने के लिए आवश्यक नहीं है मुझे लगता है कि यह सच है अगर मैं वापस कदम। हालांकि, मैं समझता हूं कि तीसरा पक्षों को प्रकाशित जानकारी या लेखों में प्रकाशित जानकारी में मेरा नाम प्रकाशित नहीं किया जाएगा। []

(iv) मैं सहमत हूं कि मैं किसी भी डेटा के उपयोग या वैज्ञानिक उद्देश्य (प्रयोजनों) के उपयोग के इस विश्लेषण से उत्पन्न परिणामों को प्रतिबंधित नहीं करेगा। []

(v) मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं। []

कानूनी रूप से स्वीकृत हस्ताक्षर (या हाथ का टिकट)

दिनांक: _____ / _____ / _____

हस्ताक्षर नाम: _____ हस्ताक्षर:

प्रतिनिधि: _____

दिनांक: _____ / _____ / _____

हस्ताक्षरित नाम: _____

शोधकर्ता के हस्ताक्षर: _____

दिनांक: _____ / _____ / _____

अध्ययन शोधकर्ता नाम: _____

गवाह के हस्ताक्षर या लिखावट: _____

दिनांक: _____ / _____ / _____

गवाह का नाम और पता: _____

অধ্যয়ন অধ্যয়ন অংশগ্রহণের জন্য ফর্ম

গবেষণায় শিরোনাম: ফুসফুস এবং ফুসফুসের ফাংশন এবং ফুসফুসে ফুসফুসের ফুসফুসে পরিবর্তনগুলি লাইফস্টাইল পরিবর্তন।

সংখ্যা: _____

সূচনা: _____

নাম: _____

জন্ম তারিখ / বয়স: _____

(i) আমি নিশ্চিত যে উপরের বিশ্লেষণের জন্য আমি _____ এর তথ্যপত্র পড়েছি এবং বুঝতে পেরেছি এবং গবেষণা সম্পর্কে প্রশ্ন করার সুযোগ পেয়েছি। []

(ii) আমি বুঝতে পারছি যে অধ্যয়নে আমার অবদান স্বতঃস্ফূর্ত এবং আমি বুঝতে পারি যে এই অধ্যয়নের থেকে কোনও কারণ ছাড়াই যে কোনও চিকিত্সা বা আইনগত অধিকার ছাড়াই আমার স্বাধীনতা আছে। []

(iii) আমি বুঝতে পারি যে এই গবেষণার উদ্দেশ্য এবং এর সঙ্গে যুক্ত কোনও গবেষণা নেতৃস্থানীয় তদন্তকারী, নীতিশাস্ত্র দল এবং নিয়ন্ত্রক কর্তৃপক্ষের জন্য আমার স্বাস্থ্যের রেকর্ড পরীক্ষা করার প্রয়োজন হয় না। আমি পিছনে ফিরে যেদি এই সত্য মনে হয়। যাইহোক, আমি বুঝতে পারি যে আমার নাম তৃতীয় পক্ষগুলিতে প্রকাশিত তথ্য বা প্রবন্ধগুলিতে প্রকাশিত তথ্যের মধ্যে প্রকাশিত হবে না। []

(iv) আমি সম্মত হচ্ছি যে আমি কোনও উপাত্ত ব্যবহার বা বিজ্ঞানের উদ্দেশ্যে (গুলি) ব্যবহারের এই বিশ্লেষণ থেকে উদ্ভূত ফলাফলকে সীমাবদ্ধ করব না। []

(v) উপরের আলোচনায় অংশগ্রহণের জন্য আমি সম্মত। []

বৈধভাবে গৃহীত স্বাক্ষর (বা হাত স্ট্যাম্প)

তারিখ: _____ / _____ / _____

স্বাক্ষর নাম: _____ স্বাক্ষর:

অথবা

প্রতনিধিি: _____

তারখি: _____ / _____ / _____

সাইন ইন নাম: _____

গবষেক এর স্বাক্ষর: _____

তারখি: _____ / _____ / _____

স্টাডি গবষেক নাম: _____

সাক্ষীর স্বাক্ষর বা স্বাক্ষর: _____

তারখি: _____ / _____ / _____

সাক্ষীর নাম এবং ঠকিানা: _____

ANNEXURE 3: Patient Information Sheet

THE EFFECT OF APPROPRIATE ATT ON RECOVERY OF PULMONARY AND PLEURAL TUBERCULOSIS AND THE IMPACT OF TUBERCULOSIS ON LUNG FUNCTION AND QUALITY OF LIFE IN NEWLY DIAGNOSED PATIENTS

1.What is the study about?

Tuberculosis is one of the most common causes for long term morbidity . Tuberculosis is caused by a bacteria, Mycobacterium tuberculosis. In both treated and untreated patients long term complications following TB infection is seen. So in this study we are going to evaluate how tuberculosis affects your lung function and quality of life . We do this by doing lung function test and filling up a questionnaire . This will be done at three occasions , before starting treatment, at 2^{nd} month and at treatment completion. By doing the tests in three different time period during your treatment course we will be able to assess your baseline lung function and improvement or worsening with treatment.

2.What will you have to do?

You will have have to fill the quality of life questionnaire and perform Pulmonary function test at 3 occasions in addition to your routine tests.

3.Are there any risks for you if you take part in the study?

No,there are no risks if you take part in this study.

4.Do you have to pay?

Pulmonary function test will be performed free of cost and you will have to pay for your routine evaluation.

5.What are the benefits to you if you take part in the study?

There will not be any direct benefit to the study participants

6.Can you decide not to participate?

Your participation in this study is entirely voluntary and you are also free to withdraw from this study any time you wish. If you do so, this will not affect your usual treatment at this hospital in any way. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

7.Will your personal details be kept confidential?

The results of this study may be published in a medical journal, but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission, should you decide to participate in this study.

If you have any further questions, please contact
Dr.Dhivya Roy , Department of Pulmonary Medicine
Email Id: dhivyaroy77@yahoo.com, Contact no - 7010367136

தகவல் தாள்

ஆய்வுக்கான தலைப்பு: நுரையீரலில் புதிதாக காசநோய் கண்டறியப்பட்ட நோயாளியின் நுரையீரலில் மருந்துகள் காரணமாக ஏற்படும் மாற்றங்கள் மற்றும் நுரையீரல் செயல்பாடுகள் மற்றும் வாழ்க்கை தரத்தில் ஏற்படும் மாற்றங்கள்.

1.இந்த படிப்பு என்ன?

நீண்ட கால நோய்க்கு மிகவும் பொதுவான காரணங்களில் ஒன்று காசநோய் ஆகும். காசநோய் என்பது மைக்கோபாக்டீரியத்தால் ஏற்படுகிறது, இது ஒரு பாக்டீரியா ஆகும். சிகிச்சையளிக்கப்படாத மற்றும் சிகிச்சை அளிக்கப்படாத நோயாளிகளில் நீண்ட கால சிக்கல்கள் TB தொற்றுக்குப் பின் ஏற்படும். இந்த ஆய்வில், உங்கள் நுரையீரல் செயல்பாடு மற்றும் வாழ்க்கை தரத்தை எவ்வாறு பாதிக்கின்றது என்பதை மதிப்பீடு செய்வோம். நாம் நுரையீரல் செயல்பாட்டு சோதனை செய்து ஒரு கேள்வித்தாள் பூர்த்தி செய்வதன் மூலம் இதை செய்யலாம். சிகிச்சையைத் தொடங்கும் முன்பு, 2 மாதத்தில், சிகிச்சை முடிந்த பின், இது மூன்று சந்தர்ப்பங்களில் செய்யப்படும். உங்கள் சிகிச்சையின் போது மூன்று வெவ்வேறு நேரங்களில் சோதனைகள் செய்வதன் மூலம் உங்கள் அடிப்படை நுரையீரல் செயல்பாடு மற்றும் மேம்பாடு அல்லது சிகிச்சையுடன் மோசமடைதல் ஆகியவற்றை மதிப்பிடுவோம்.

2. நீங்கள் என்ன செய்ய வேண்டும்?

உங்கள் வழக்கமான சோதனைகளுக்கு கூடுதலாக 3 சந்தர்ப்பங்களில் வாழ்க்கை கேள்வியின் தரத்தை நிரப்பவும் நுரையீரல் செயல்பாட்டு சோதனை செய்யவும் வேண்டும்.

3. நீங்கள் படிப்பில் பங்கு பெற்றால் உங்களுக்கு என்ன ஆபத்துகள்?

இந்த ஆய்வில் பங்கேற்க உங்களுக்கு எந்த ஆபத்தும் இல்லை.

4. நீங்கள் பணம் செலுத்த வேண்டும்வா?

நுரையீரல் செயல்பாடு சோதனை இலவசமாக செய்யப்படும் மற்றும் உங்கள் வழக்கமான விசாரணைக்கு பணம் செலுத்த வேண்டும்.

5. நீங்கள் படிப்பில் பங்கு பெற்றால் என்ன நன்மை?

ஆய்வு பங்கேற்பாளர்களுக்கு நேரடியான பயன் இல்லை

6.ஆனால் நீங்கள் பங்கேற்க விரும்பமாட்டீர்களா?

இந்த ஆய்வில் நீங்கள் பங்குபெற்றிருப்பது முற்றிலும் தன்னார்வத் தொண்டு ஆகும், மேலும் இந்த ஆய்வின்படி உங்கள் விருப்பப்படி எந்த நேரத்திலும் நீங்கள் திரும்பப் பெறலாம். நீங்கள் அவ்வாறு செய்தால், இது உங்கள் வழக்கமான சிகிச்சையை எந்த வகையிலும் இந்த மருத்துவமனையில் பாதிக்காது. உங்கள் மருத்துவர் இன்னும் உங்களை கவனித்துக்கொள்வார், நீங்கள் எந்த நன்மைகளை இழக்க மாட்டீர்கள்.

7. உங்கள் தனிப்பட்ட விவரங்கள் இரகசியமாக வைக்கப்படுமா?

இந்த ஆய்வின் முடிவுகள் மருத்துவ இதழில் வெளியிடப்படலாம், ஆனால் உங்கள் பெயர் வெளியிடப்படாது. ஆயினும், இந்த ஆய்வில் கலந்துகொள்ள நீங்கள் முடிவு செய்ய விரும்பினால், கூடுதல் மருத்துவ அனுமதியில்லாமல் உங்கள் மருத்துவ குறிப்புகள், ஆய்வு தொடர்பான நபர்களால் மதிப்பாய்வு செய்யப்படலாம்.

உங்களுக்கு ஏதாவது கேள்விகள் இருந்தால், தயவுசெய்து தொடர்பு கொள்ளவும்

டாக்டர் Dhivya Roy , நுரையீரல் மருத்துவம் துறை

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सूचना शीट

अध्ययन का शीर्षक: फेफड़े में फेफड़े के नये फेफड़े के मरीजों के फेफड़ों में फेफड़े और फेफड़े के कार्यों और जीवन शैली के परिवर्तन में परिवर्तन।

1. यह अध्ययन क्या है?

दीर्घकालिक बीमारी के सबसे सामान्य कारणों में से एक तपेदिक है क्षयरोग के कारण मायकोबैक्टीरियम होता है, जो कि बैक्टीरिया है टीबी संक्रमण के बाद अनुपचारित और अनुपचारित मरीजों में दीर्घकालिक जटिलताएं आ जाएंगी। इस अध्ययन में हम मूल्यांकन करेंगे कि आपके फेफड़ों के कार्य और जीवन की गुणवत्ता को प्रभावित कैसे किया जाता है। हम इसे फेफड़ों के फ़ंक्शन को जांच कर एक प्रश्नावली को पूरा करके कर सकते हैं। उपचार के 2 महीने के बाद, इलाज शुरू होने से पहले तीन मौकों पर उपचार किया जाएगा। हम आपके उपचार के दौरान तीन अलग-अलग समय पर परीक्षणों को निष्पादित करके अपने मूल फेफड़ों के कार्य और इलाज या उपचार के साथ गिरावट का मूल्यांकन करते हैं।

2. आपको क्या करना है?

आपके नियमित प्रयोगों के अतिरिक्त, आपको 3 मामलों में जीवन की गुणवत्ता और फेफड़े के फ़ंक्शन परीक्षण को पूरा करना होगा।

3. यदि आप अध्ययन में भाग लेते हैं तो आपके पास क्या खतरा है?

इस अध्ययन में भाग लेने के लिए आपको कोई जोखिम नहीं है।

4. क्या आपको भुगतान करना है?

फेफड़ों का फ़ंक्शन नि: शुल्क परीक्षण किया जाएगा और आपके नियमित परीक्षण के लिए भुगतान करेगा।

5. यदि आपने अध्ययन में भाग लिया है तो क्या होगा?

अध्ययन प्रतिभागियों का प्रत्यक्ष लाभ नहीं है

6.तुम भाग लेने के लिए पसंद नहीं करते हैं?

इस अध्ययन में आपकी भागीदारी पूरी तरह से स्वैच्छिक है और इस अध्ययन के अनुसार आप अपनी पसंद के किसी भी समय वापस ले सकते हैं। यदि आप ऐसा करते हैं, तो यह किसी भी अस्पताल में आपके नियमित उपचार को प्रभावित नहीं करेगा। आपका डॉक्टर अब भी आपकी देखभाल करेगा और आप कोई लाभ नहीं खोेंगे

7. क्या आपकी व्यक्तिगत जानकारी गुप्त रखी जाएगी?

इस अध्ययन के परिणाम एक चिकित्सा पत्रिका में प्रकाशित किए जा सकते हैं, लेकिन आपका नाम प्रकाशित नहीं किया जाएगा। हालांकि, यदि आप इस अध्ययन में भाग लेने का निर्णय करना चाहते हैं, तो आपके चिकित्सा सुझावों की समीक्षा उन शोधकर्ताओं द्वारा की जा सकती है जिनके पास कोई अतिरिक्त चिकित्सा अनुमति नहीं है।

यदि आपके कोई प्रश्न हैं, तो कृपया संपर्क करें

डॉ। धीवया रॉय, फेफड़े मेडिकल विभाग

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তথ্য পত্রক

গবষেণায় শরিোনাম: ফুসফুসরে ফুসফুস এবং ফুসফুসরে ফাংশন এবং লাইফস্টাইল পরবির্তনগুলি নতুন ফুসফুসরে রোগীদরে ফুসফুসরে পরবির্তন।

1. এই অধ্যয়ন কি?

দীর্ঘমেয়াদী অসুস্থতার সবচয়েে সাধারণ কারণ হল যক্ষ্মা। যক্ষ্মা মাইকোব্যাকটরেিয়াম দ্বারা সৃষ্ট হয়, যা একটি ব্যাকটরেিয়া। টবিি সংক্রমণরে পর নরিাময়হীন ও নরিাময় রোগীদরে দীর্ঘমেয়াদী জটলিতা দখো দতিে পার। এই গবষেণায় আমরা কভিাবে আপনার ফুসফুস ফাংশন এবং জীবন মান প্রভাবতি হয় মূল্যায়ন করা হব। আমরা ফুসফুস ফাংশনটি চকে করে একটি প্রশ্নাবলী পূর্ণ করে এটি করতে পারি। চকিত্সার 2 মাস পর, চকিত্সা শুরু হওয়ার আগে তনিবার চকিত্সা করা হব। আপনার চকিত্সার সময় আপনার মৌলকি ফুসফুস ফাংশন এবং তনিটি ভন্নি সময়ে ট্রায়াল সম্পাদন করে চকিত্সা বা চকিত্সার সাথে নবিড়িতা নর্িণয় করুন।

2. আপনি কি করতে হব?

আপনার নয়িমতি পরীক্ষার পাশাপাশি, 3 টি ক্ষত্রেে আপনার জীবনরে গুণমান এবং ফুসফুস ফাংশন পরীক্ষা সম্পূর্ণ করতে হব।

3. আপনি অধ্যয়ন অংশগ্রহণ যদি আপনি কি ঝুঁকি আছ?

এই গবষেণায় অংশ নতিে আপনার কোনও ঝুঁকি নইে।

4. আপনি কি দতিে হব?

ফুসফুস ফাংশন বনিামূল্যে জন্য পরীক্ষা করা হবে এবং আপনার নয়িমতি পরীক্ষা জন্য অর্থ প্রদান করা হব।

5. আপনি যদি অধ্যয়নে অংশগ্রহণ করনে তবে কী হব?

অধ্যয়ন অংশগ্রহণকারীদরে সরাসরি উপকার হয় না

6.আপনি অংশগ্রহণ করতে পছন্দ করনে না?

এই গবষেণায় আপনার অংশগ্রহণ একবোরে স্বচ্ছোসবেী এবং আপনি এই গবষেণায় অনুযায়ী আপনার পছন্দরে যে কোন সময় প্রত্যাহার করতে পারনে। আপনি যদি তা করনে তবে এটি আপনার হাসপাতালে কোনও রুটনি চকিত্সার উপর প্রভাব ফলেব না। আপনার ডাক্তার এখনও আপনার জন্য যত্ন নবেনে এবং আপনি কোন বনেফিটি হারাবনে না।

7. আপনার ব্যক্তগিত ববিরণ গোপন রাখা হব?

এই গবষেণা ফলাফল একটি মডেকিলে জার্নাল প্রকাশতি হতে পার, কন্িতু আপনার নাম প্রকাশতি হবে না। যাইহোক, যদি আপনি এই গবষেণায় অংশ নওেয়ার সদ্িধান্ত নতিে চান, তবে অতরিক্িত চকিৎিসার অনুমতি ছাড়াই সংশ্লষ্টি ব্যক্তরিা আপনার চকিৎিসা সংক্রান্ত পরামর্শগুলি পর্যালোচনা করতে পারবনে।

আপনার যদি কোনো প্রশ্ন থাক, তাহলে যোগাযোগ করুন

ড। ধাইয়া রায়, লং মডেকি্যাল ডপিার্টমন্টে

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Annexure 4: Data abstraction sheet

QUESTIONNAIRE

CASE REPORT FORM -PTB

IRB NO ☐ DEPARTMENT ☐ CENTER ☐ SUBJECT ID ☐

DATE OF VISIT

☐☐☐☐ ☐☐ ☐☐

Y Y Y Y M M D D

DEMOGRAPHGIC DETAILS:

AGE ☐☐ YEARS

SEX ☐ 1.MALE ☐ 2.FEMALE

BMI ☐☐ WEIGHT ☐ HEIGHT

VISIT 1 - BASELINE

SYMPTOMATOLOGY:

COUGH ☐ 1 YES ☐ 2 NO

IF YES, DURATION ☐☐ MONTHS/ YEARS

HEMOPTYSIS ☐ 1 YES ☐ 2 NO

FEVER ☐ 1 YES ☐ 2 NO

LOSS OF APETITE ☐ 1 YES ☐ 2 NO

LOSS OF WEIGHT ☐ 1 YES ☐ 2 NO

BREATHLESSNESS ☐ 1 YES ☐ 2 NO

PLEURITIC CHEST PAIN ☐ 1 YES ☐ 2 NO

COMORBIDITIES

SMOKING ☐ 1 NEVER ☐ 2 FORMER ☐ 3 CURRENT

PACK YEARS ☐ YEARS

DIABETES MELLITUS ☐ 1 YES ☐ 2 NO

HIV ☐ 1 YES ☐ 2 NO

COPD ☐ 1 YES ☐ 2 NO

ASTHMA ☐ 1 YES ☐ 2 NO

PAST HISTORY:

HISTORY OF TB ☐ 1 YES ☐ 2 NO

IF YES, WHEN ☐ YEARS/ MONTHS

☐ 1 PULMONARY TB ☐ 2 PLEURAL TB

ATT TAKEN BEFORE ☐ 1 YES ☐ 2 NO

ATT COMPLETED ☐ 1 YES ☐ 2 NO

NUMBER OF PRIOR ATT INTAKE ☐ 1 ONE TIME ☐ 2 TWO OR MORE

EXAMINATION:

HEIGHT ☐☐☐ CM

WEIGHT ☐☐ KG BP ☐☐ MM/HG

CREPITATION ☐ 1 YES ☐ 2 NO

BBS ☐ 1 YES ☐ 2 NO

INVESTIGATIONS:

HEMOGLOBIN ☐1.NORMAL ☐2. >10 ☐3. >7 ☐4.<7

HBAIC ☐1.NORMAL <5.6 ☐2. <7.5 ☐3. <10 ☐4.>1O

SPUTUM AFB ☐ 1. POSITIVE ☐ 2. NEGATIVE

SEVERITY OF POSITIVITY ☐ 1.SCANTY ☐ 2. 1+ ☐ 3. 2+ ☐ 4. 3+

SPUTUM XPERT ☐ 1. POSITIVE ☐ 2. NEGATIVE

SEVERITY ☐ 1. VERY LOW ☐ 2. LOW ☐ 3. MODERATE ☐ 4.HEAVY

MGIT/L J ☐ 1. MTB GROWN ☐ 2. NO GROWTH

FIRST LINE DST ☐ 1. PAN SENSITIVE ☐ 2. ANY RESISTANCE-_____

BAL AFB ☐ 1. POSITIVE ☐ 2. NEGATIVE

SEVERITY OF POSITIVITY ☐ 1.SCANTY ☐ 2. 1+ ☐ 3. 2+ ☐ 4. 3+

BAL XPERT ☐ 1. POSITIVE ☐ 2. NEGATIVE

SEVERITY ☐ 1. VERY LOW ☐ 2. LOW ☐ 3. MODERATE ☐ 4.HEAVY

TBLB XPERT ☐ 1. POSITIVE ☐ 2. NEGATIVE

TBLB HPE ☐ 1. NECROTISING GRANULOMATOUS INFLAMMATION

☐ 2. OTHERS _____

CHEST XRAY:

CHEST X-RAY	☐**Not done, participant pregnant**	☐**Not done, other reason**

1. Date of Chest X-Ray: ☐☐-☐☐☐-☐☐☐☐

2. Chest X-Ray Findings:

		Right	Left
Lung Opacity (Shadows)	Upper Zone (Apex to anterior end of 2nd rib)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
	Mid Zone (2nd to 4th rib)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
	Lower Zone (Anterior end of 4th rib to diaphragm)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
Mediastinal Adenopathy		☐Present ☐Absent	☐Present ☐Absent
Pleural Effusion		☐Present ☐Absent	☐Present ☐Absent

Chest X-Ray Score

3a. Percentage of lung affected: ☐☐☐%

3b. Is cavitation present? ☐ Yes, 40 points ☐ No, 0 points

3c. Score (3a + 3b) ☐☐☐points ***(range: 0 – 140 points)***

PULMONARY FUNCTION TESTS

DATE:

	PREDICTED	LLN OF PRED	POST BRONCHOD	%(POST/PRED)
FVC				
FEV1				
FEV1/FVC				
PEF				
MMEF				
FET				
PIF				

INTERPRETATION: ☐ 1.NORMAL ☐ 2. OBSTRUCTION ☐ 3. RESTRICTION

☐ 4. MIXED ☐ 5. OTHERS _____

ST GEORGE'S RESPIRATORY QUESTIONNAIRE FOR QUALITY OF LIFE

SYMPTOM DOMAIN SCORE ☐☐ . ☐

ACTIVITY DOMAIN SCORE ☐☐ . ☐

IMPACT DOMAIN SCORE ☐☐ . ☐

TOTAL SCORE ☐☐ . ☐

VISIT 2 – 2ND MONTH

DATE OF VISIT

☐☐☐☐ ☐☐ ☐☐
YYYY MM DD

COUGH ☐ 1. IMPROVED ☐ 2. PERSISTENT

FEVER ☐ 1. IMPROVED ☐ 2. PERSISTENT

OTHER SYMPTOMS ☐ 1. IMPROVED ☐ 2. PERSISTENT _____

WEIGHT GAIN ☐ 1.PRESENT ☐ 2. ABSENT ☐ 3. SAME WT _____

ANY SIDE EFFECT TO ATT ☐ 1.YES ☐ 2. NO

IF YES ☐ 1. GASTRITIS ☐ 2. HEPATITIS ☐ 3. OTHERS _____

CREPITATIONS ☐ 1.PRESENT ☐ 2. ABSENT

SPUTUM AFB ☐ 1. POSITIVE ☐ 2. NEGATIVE

SEVERITY OF POSITIVITY ☐ 1.SCANTY ☐ 2. 1+ ☐ 3. 2+ ☐ 4. 3+

LFT ☐ 1.NORMAL ☐ 2. HEPATITIS

CHEST XRAY:

CHEST X-RAY	☐ **Not done, participant pregnant**	☐ **Not done, other reason**

3. Date of Chest X-Ray: ☐☐-☐☐☐-☐☐☐☐

4. Chest X-Ray Findings:

		Right	Left
Lung Opacity (Shadows)	Upper Zone (Apex to anterior end of 2nd rib)	☐ 1 Cavitation ☐ 2 Opacity (shadows other than cavitation) ☐ 3 No opacity (no shadows)	☐ 1 Cavitation ☐ 2 Opacity (shadows other than cavitation) ☐ 3 No opacity (no shadows)

	Mid Zone (2nd to 4th rib)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
	Lower Zone (Anterior end of 4th rib to diaphragm)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
Mediastinal Adenopathy		☐Present ☐Absent	☐Present ☐Absent
Pleural Effusion		☐Present ☐Absent	☐Present ☐Absent

Chest X-Ray Score

3a. Percentage of lung affected: ☐☐☐%

3b. Is cavitation present? ☐ Yes, 40 points ☐ No, 0 points

3c. Score (3a + 3b) ☐☐☐points ***(range: 0 – 140 points)***

SPIROMETRY : DATE:

	PRED	PRE	%(PRE/PRED)	POST	%POST/PRED	D%(POST/PRE)
FVC						
FEV1						
FEV1/FVC						
PEF						
MMEF						
FET						
PIF						

INTERPRETATION: ☐1.NORMAL ☐2. OBSTRUCTION ☐3. RESTRICTION

☐4. MIXED ☐5. OTHERS _____

DLCO

	PRED	PRE	%(PRE/PRED)
DLCO SB			
DLCOc SB			

VA			
DLCO/VA			
DLCOc/VA			

INTERPRETATION:

☐ 1.NORMAL ☐ 2. REDUCED

LUNG VOLUMES

	PRED	PRE	%(PRE/PRED)
DLCO SB			
DLCOc SB			
VA			
DLCO/VA			
DLCOc/VA			
FRC-He			
RV-He			
TLC-He			
RV % TLC- He			

INTERPRETATION: ☐ 1.NORMAL ☐ 2. REDUCED

ST GEORGE'S RESPIRATORY QUESTIONNAIRE FOR QUALITY OF LIFE

SYMPTOM DOMAIN SCORE ☐☐.☐

ACTIVITY DOMAIN SCORE ☐☐.☐

IMPACT DOMAIN SCORE ☐☐.☐

ATT REGIMEN

☐ 1. HRE ☐ 2. SLE ☐ 3. OTHERS _____

INH _____mg , RIFAMPICIN_____mg, PYRAZINAMIDE_____mg,ETHAMBUTOL_____mg

STREPTOMYCIN_____mg, LEVOFLOXACIN _____mg, ETHAMBUTOL_____mg

OTHERS_____

VISIT 3 – 6th MONTH

DATE OF VISIT

☐☐☐☐ ☐☐ ☐☐
YYYY MM DD

COUGH ☐ 1. IMPROVED ☐ 2. PERSISTENT

FEVER ☐ 1. IMPROVED ☐ 2. PERSISTENT

OTHER SYMPTOMS ☐ 1. IMPROVED ☐ 2. PERSISTENT _____

WEIGHT GAIN ☐ 1.PRESENT ☐ 2. ABSENT ☐ 3. SAME WT _____

ANY SIDE EFFECT TO ATT ☐ 1.YES ☐ 2. NO

IF YES ☐ 1. GASTRITIS ☐ 2. HEPATITIS ☐ 3. OTHERS _____

CREPITATIONS ☐ 1.PRESENT ☐ 2. ABSENT

SPUTUM AFB ☐ 1. POSITIVE ☐ 2. NEGATIVE

LFT ☐ 1.NORMAL ☐ 2. HEPATITIS

CHEST XRAY:

CHEST X-RAY ☐ **Not done, participant pregnant** ☐ **Not done, other reason**

1. Date of Chest X-Ray: ☐☐-☐☐☐-☐☐☐☐

2. Chest X-Ray Findings:

		Right	Left
Lung Opacity (Shadows)	Upper Zone (Apex to anterior end of 2nd rib)	☐ 1 Cavitation ☐ 2 Opacity (shadows other than cavitation) ☐ 3 No opacity (no shadows)	☐ 1 Cavitation ☐ 2 Opacity (shadows other than cavitation) ☐ 3 No opacity (no shadows)

	Mid Zone (2nd to 4th rib)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
	Lower Zone (Anterior end of 4th rib to diaphragm)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
Mediastinal Adenopathy		☐Present ☐Absent	☐Present ☐Absent
Pleural Effusion		☐Present ☐Absent	☐Present ☐Absent

Chest X-Ray Score

3a. Percentage of lung affected: ☐☐☐%

3b. Is cavitation present? ☐ Yes, 40 points ☐ No, 0 points

3c. Score (3a + 3b) ☐☐☐points ***(range: 0 – 140 points)***

SPIROMETRY : DATE:

	PRED	PRE	%(PRE/PRED)	POST	%POST/PRED	D%(POST/PRE)
FVC						
FEV1						
FEV1/FVC						
PEF						
MMEF						
FET						
PIF						

INTERPRETATION: ☐1.NORMAL ☐2. OBSTRUCTION ☐3. RESTRICTION

☐4. MIXED ☐5. OTHERS _____

DLCO

	PRED	PRE	%(PRE/PRED)
DLCO SB			
DLCOc SB			

VA			
DLCO/VA			
DLCOc/VA			

INTERPRETATION: ☐ 1.NORMAL ☐ 2. REDUCED

LING VOLUMES

	PRED	PRE	%(PRE/PRED)
DLCO SB			
DLCOc SB			
VA			
DLCO/VA			
DLCOc/VA			
FRC-He			
RV-He			
TLC-He			
RV % TLC- He			

INTERPRETATION: ☐ 1.NORMAL ☐ 2. REDUCED

ST GEORGE'S RESPIRATORY QUESTIONNAIRE FOR QUALITY OF LIFE

SYMPTOM DOMAIN SCORE ☐☐.☐

ACTIVITY DOMAIN SCORE ☐☐.☐

IMPACT DOMAIN SCORE ☐☐.☐

St. George's Respiratory Questionnaire
PART 1

Questions about how much chest problem you have had over the past 4 weeks.

Please checkmark (✔) *one box for each question*:

	Most days a week	Several days a week	A few days a month	Only with chest infections	Not at all
1. Over the past 4 weeks, I have coughed:	☐	☐	☐	☐	☐
2. Over the past 4 weeks, I have brought up phlegm (sputum):	☐	☐	☐	☐	☐
3. Over the past 4 weeks, I have had shortness of breath:	☐	☐	☐	☐	☐
4. Over the past 4 weeks, I have had attacks of wheezing:	☐	☐	☐	☐	☐

5. During the past 4 weeks, how many severe or very unpleasant attacks of chest problem have you had?

Please checkmark (✔) *one box only*:

- more than 3 attacks ☐
- 3 attacks ☐
- 2 attacks ☐
- 1 attack ☐
- no attacks ☐

6. How long did the worst attack of chest problem last:
(Go to question 7 if you had no severe attacks)

Please checkmark (✔) *one box only*:

- a week or more ☐
- 3 days or more ☐
- 1 or 2 days ☐
- Less than a day ☐

7. Over the past 4 weeks, in an average week, how many good days (with little chest problem) have you had:

Please checkmark (✔) *one box only*:

- No good days ☐
- 1 or 2 good days ☐
- 3 or 4 good days ☐
- Nearly every day was good ☐
- Every day was good ☐

8. If you have a wheeze, is it worse in the morning:

Please checkmark (✔) *one box only*:

- No ☐
- Yes ☐

St. George's Respiratory Questionnaire
PART 2

Section 1

How would you describe your chest condition?

Please checkmark (✔) *one box only*:

- The most important problem I have ☐
- Causes me quite a lot of problems ☐
- Causes me a few problems ☐
- Causes me no problem ☐

If you have ever had paid employment.

Please checkmark (✔) *one box only*:

- My chest problem made me stop work altogether ☐
- My chest problem interferes with my work or made me change my work ☐
- My chest problem does not affect my work ☐

Section 2

Questions about what activities usually make you feel breathless <u>these days</u>.

For ***each item***, please checkmark (✔) the box as it applies to you ***these days***:

	True	False
Sitting or lying still	☐	☐
Getting washed or dressed	☐	☐
Walking around at home	☐	☐
Walking outside on the level	☐	☐
Climbing up a flight of stairs	☐	☐
Climbing hills	☐	☐
Playing sports or games	☐	☐

St. George's Respiratory Questionnaire
PART 2

Section 3

Some more questions about your cough and breathlessness <u>these days</u>.

	For ***each item***, please checkmark (✓) the box as it applies to you ***these days***: True	False
My cough hurts	☐	☐
My cough makes me tired	☐	☐
I am breathless when I talk	☐	☐
I am breathless when I bend over	☐	☐
My cough or breathing disturbs my sleep	☐	☐
I get exhausted easily	☐	☐

Section 4

Questions about other effects that your chest problem may have on you <u>these days</u>.

	For ***each item***, please checkmark (✓) the box as it applies to you ***these days***: True	False
My cough or breathing is embarrassing in public	☐	☐
My chest problem is a nuisance to my family, friends or neighbours	☐	☐
I get afraid or panic when I cannot get my breath	☐	☐
I feel that I am not in control of my chest problem	☐	☐
I do not expect my chest to get any better	☐	☐
I have become frail or an invalid because of my chest	☐	☐
Exercise is not safe for me	☐	☐
Everything seems too much of an effort	☐	☐

Section 5

Questions about your medication. If you are taking no medication go straight to Section 6.

	For ***each item***, please checkmark (✓) the box as it applies to you ***these days***: True	False
My medication does not help me very much	☐	☐
I get embarrassed using my medication in public	☐	☐
I have unpleasant side effects from my medication	☐	☐
My medication interferes with my life a lot	☐	☐

St. George's Respiratory Questionnaire
PART 2

Section 6

These are questions about how your activities might be affected by your breathing.

For ***each item***, please checkmark (✓) the box as it applies to you ***because of your breathing***:

	True	False
I take a long time to get washed or dressed	☐	☐
I cannot take a bath or shower, or I take a long time	☐	☐
I walk slower than other people, or I stop for rests	☐	☐
Jobs such as housework take a long time, or I have to stop for rests	☐	☐
If I walk up one flight of stairs, I have to go slowly or stop	☐	☐
If I hurry or walk fast, I have to stop or slow down	☐	☐
My breathing makes it difficult to do things such as climbing up hills, carrying things up stairs, light gardening such as weeding, dancing, playing bowls or golf	☐	☐
My breathing makes it difficult to do things such as carrying heavy loads, digging the garden or shovelling snow, jogging or walking at 8 kilometres per hour, playing tennis or swimming	☐	☐
My breathing makes it difficult to do things such as very heavy manual work, running, cycling, swimming fast or playing competitive sports	☐	☐

Section 7

We would like to know how your chest problem <u>usually</u> affects your daily life.

For ***each item***, please checkmark (✓) the box as it applies to you ***because of your chest problem***:

	True	False
I cannot play sports or games	☐	☐
I cannot go out for entertainment or recreation	☐	☐
I cannot go out of the house to do the groceries	☐	☐
I cannot do housework	☐	☐
I cannot move far from my bed or chair	☐	☐

St. George's Respiratory Questionnaire

Here is a list of other activities that your chest problem may prevent you doing (you do not have to checkmark these, they are just to remind you of ways in which your breathlessness may affect you):

Going for walks or walking the dog

Doing things at home or in the garden

Sexual intercourse

Going out to church or place of entertainment

Going out in bad weather or into smoky rooms

Visiting family or friends or playing with children

Please write in any other important activities that your chest problem may stop you doing:

. . . . . .

. . . . . .

. . . . . .

. . . . . .

Now, would you checkmark the box (one only) which you think best describes how your chest affects you:

It does not stop me doing anything I would like to do ☐

It stops me doing one or two things I would like to do ☐

It stops me doing most of the things I would like to do ☐

It stops me doing everything I would like to do ☐

Thank you for filling in this questionnaire. Before you finish, would you check to see that you have answered all the questions.

CHEST X-RAY FORM

Participant ID: ☐☐☐-☐☐☐☐☐-☐ Visit Date: ☐☐-☐☐☐-☐☐☐☐

D D M O N Y Y Y Y

Site ID: ☐☐☐

Visit Type: ☐ Baseline ☐ Month 2 ☐ End of TX

CHEST X-RAY ☐ **Not done, participant pregnant** ☐ **Not done, other reason**

1. Date of Chest X-Ray: ☐☐-☐☐☐-☐☐☐☐ (D D M O N Y Y Y Y)

2. Chest X-Ray Findings:

		Right	Left
Lung Opacity (Shadows)	Upper Zone (Apex to anterior end of 2nd rib)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
	Mid Zone (2nd to 4th rib)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)

	Lower Zone (Anterior end of 4th rib to diaphragm)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)	☐1 Cavitation ☐2 Opacity (shadows other than cavitation) ☐3 No opacity (no shadows)
Mediastinal Adenopathy		☐Present ☐Absent	☐Present ☐Absent
Pleural Effusion		☐Present ☐Absent	☐Present ☐Absent

3. Chest X-Ray Score

3a. Percentage of lung affected: ☐☐☐%

3b. Is cavitation present? ☐ Yes, 40 points ☐ No, 0 points

3c. Score (3a + 3b) ☐☐☐points ***(range: 0 – 140 points)***

ANNEXURE 5: THESIS DATA

slno	hospno	name	ethnicity	age	sex	bmi	tbtype	cough	coughdur	hemoptysis	fever	appetite	weightloss	breath	chestpain	smoking	smoke	packyears	dm	hiv	COPD	asthma	tbhistory	tbwhen	pasttb
1	180617h	MARIMUTHU	South	45	Male	18.4	Pulmonary	Yes	1	Yes	Yes	Yes	Yes	No	Yes	Current	Beedi	25	No	No	No	No	No		
2	597536G	CHITRA PALANIVEL	South	24	Female	16.9	Pulmonary	Yes	3	No	Yes	Yes	Yes	Yes	Yes	Never			No	No	No	No	No		
3	167096H	DINESH PRASAD	East	42	Male	24.2	pleura	Yes	1	No	Yes	Yes	Yes	Yes	Yes	Never			No	No	No	No	No		
4	143056H	VELAYUTHAM	South	26	Male	17.2	Pulmonary	Yes	3	No	Yes	Yes	Yes	Yes	Yes	Never			No	No	No	No	No		
5	180116H	KAKALI BISWAS	East	54	Female	26	Pulmonary	Yes	3	No	Yes	Yes	Yes	Yes	No	Never			No	No	No	No	Yes	14	Pulmonary
6	181864H	SAINIK ATHAK	East	23	Male	19.3	Pulmonary	Yes	2	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
7	168096H	URMILA DEVI	East	58	Female	16.7	Pulmonary	Yes	3	No	No	No	No	No	No	Never			No	No	No	No	No		
8	193187H	SUFIA AKTER	Bangladesh	48	Female	22.6	Pulmonary	Yes	6	No	Yes	Yes	Yes	No	Yes	Never			Yes	No	No	No	No		
9	182844H	VIMALA	South	41	Female	15.6	Pulmonary	Yes	10	No	Yes	Yes	Yes	No	Yes	Never			No	No	No	No	No		
10	893654F	MEGANATHAN	South	37	Male	17.4	Pulmonary	Yes	2	No	Yes	Yes	Yes	No	Yes	Never			No	No	No	No	No		
11	226728H	DHANALAKSHMI	South	35	Female	20.4	Pulmonary	Yes	1	No	Yes	No	No	No	No	Never			Yes	No	No	No	No		
12	184122H	USHA BISHWAKARMA	East	43	Female	22.2	Pulmonary	Yes	4	Yes	No	No	Yes	Yes	No	Never			Yes	No	No	No	No		
13	224770H	MANJULA	South	24	Female	19	Pulmonary	Yes	2	No	No	No	No	No	Yes	Never			No	No	No	No	No		
14	210827H	RAAGUL	South	19	Male	14.5	Pulmonary	Yes	7	No	Yes	Yes	Yes	No	Yes	Never			No	No	No	No	No		
15	548932F	PRIYANKA	South	24	Female	16.46	pleura	Yes	1	No	Yes	No	No	No	Yes	Never			No	No	No	No	No		
16	236879H	PRADIP PANDIT	East	21	Male	16.7	Pulmonary	Yes	2	Yes	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
17	239397H	MUTHU	South	47	Male	17.3	Pulmonary	Yes	3	No	Yes	Yes	Yes	Yes	No	Never			No	No	No	No	No		
18	198766H	KALAIMATHI	South	56	Female	15.2	Pulmonary	Yes	12	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
19	240443H	HEMACHANDRA	South	23	Male	15.7	Pulmonary	Yes	4	Yes	Yes	Yes	Yes	Yes	No	Never			No	No	No	No	No		
20	184633H	SHAIK ABDUL RAHMAN	South	54	Male	17.1	Pulmonary	No		No	No	Yes	Yes	Yes	Yes	Current	Cigarette	60	No	No	No	No	No		
21	238665H	NURUL MD	Bangladesh	24	Male	19.2	Pulmonary	Yes	12	No	No	Yes	Yes	Yes	Yes	Never			No	No	No	No	No		
22	241071H	RATAN KUMAR BAGULI	East	44	Male	20.7	Pulmonary	Yes	12	Yes	No	No	No	No	No	Current	Cigarette	10	No	No	No	No	No		
23	979278B	RAVICHANDRAN	South	51	Male	20.9	Pulmonary	Yes	3	No	No	No	Yes	No	No	Never			Yes	No	No	No	No		
24	246393H	BINAY KUMAR MAIH	East	46	Male	15	Pulmonary	Yes	1	No	No	Yes	Yes	No	No	Never			Yes	No	No	No	Yes	1	Pulmonary
25	244000H	BALAJI	South	20	Male	15.9	pleura	Yes	6	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
26	187084H	SRINIVASAN	South	20	Male	20.1	Pulmonary	Yes	6	Yes	No	Yes	No	Yes	Yes	Former	Cigarette	15	Yes	No	No	No	No		
27	269143H	SOLOMON	South	34	Male	25.4	Pulmonary	Yes	2	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
28	494984F	ADHI NARAYANA REDDY	South	58	Male	23.7	Pulmonary	Yes	6	No	Yes	Yes	Yes	No	No	Never			Yes	No	No	No	No		
29	271163H	ARDHANDU DHAS	East	45	Male	21.2	pleura	Yes	1	No	Yes	Yes	Yes	Yes	Yes	Never			No	No	No	No	No		
30	238730H	SIMI AJMERA	East	20	Female	15.6	Pulmonary	Yes	2	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
31	282540H	JAGANNATH PRASAD	East	66	Male	25.7	Pulmonary	Yes	6	No	No	Yes	Yes	Yes	Yes	Never			Yes	No	No	No	No		
32	296868H	VASANTHI	South	48	Female	21.5	Pulmonary	Yes	1	No	Yes	No	Yes	No	No	Never			Yes	No	No	No	No		
33	276446H	ROHIT KUMAR	East	25	Male	16.8	Pulmonary	Yes	2	No	Yes	Yes	Yes	Yes	Yes	Never			No	No	No	No	No		
34	189115H	TAMILVANNAN	South	44	Male	15.4	Pulmonary	Yes	3	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
35	513498F	CHINABBA	South	59	Male	20.3	Pulmonary	No		No	Yes	Yes	No	No	No	Never			No	No	No	No	Yes	3	Pulmonary
36	301995H	SUBRAMANI	South	62	Male	15.2	Pulmonary	Yes	2	No	Yes	Yes	Yes	No	Yes	Current	Beedi	20	No	No	No	No	No		
37	246711H	CHANDAN	East	23	Male	22.5	pleura	Yes	2	Yes	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
38	271927H	AYSHA	South	38	Female	16.9	Pulmonary	Yes	1	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
39	189341H	NAGARAJAN	South	47	Male	14.5	Pulmonary	Yes	1	No	No	No	No	No	No	Current	Beedi	7	Yes	No	No	No	No		
40	936856G	VIJAYAKUMAR	North	26	Male	19.9	pleura	Yes	1	No	Yes	No	No	Yes	Yes	Never			No	No	No	No	No		
41	309595H	JUGALRAM	East	46	Male	15.2	Pulmonary	Yes	3	Yes	Yes	Yes	Yes	Yes	No	Current	Cigarette	13	Yes	No	No	No	No		
42	351029H	TRISHNA SAIKIA	East	23	Female	20.2	Pulmonary	Yes	6	Yes	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
43	189526H	JYOHKA AGARWAL	East	22	Female	20.25	Pulmonary	Yes	2	No	Yes	Yes	Yes	Yes	No	Never			No	No	No	No	No		
44	099660H	JAYANTHI	South	23	Female	15.5	Pulmonary	Yes	1	No	Yes	Yes	Yes	Yes	No	Never			No	No	No	No	No		

beforeatt	attcomp	prioratt	height	weight	sysbp	diasbp	crepit	bbs	hb	hba1c	sputumafb	afbsevere	spuxpert	sevxpert	mgit	firstline	balafb	balafbsev	balxpert	balxpertsev	tblbxpert	tblbsev	tblbhpe	PFP	pfpglucose
			160	50	100	70	No	No	10.1	5.5	Positive	1+	Positive	Moderate	MTB grown	Pan sensitive									
			165	46	100	70	Yes	No	7.9	5.3	Positive	Scanty	Positive	Low	MTB grown	Pan sensitive									
			169	64	130	80	No	No	13.1	6.1														6	99
			158	43	110	70	No	No	10.8	5.1	Positive	1+	Positive	Moderate	MTB grown	Pan sensitive									
Yes	Yes	1 time	152	60	130	70	No	No	10.1	5.5	Positive	Scanty	Negative		MTB grown	Pan sensitive									
			175	59	110	70	No	No	14.5	5.2	Negative		Positive	Very low	MTB grown	Pan sensitive									
			147	36	90	60	No	No	9.6	6.3	Negative		Positive	Very low	MTB grown	Pan sensitive									
No			153	53	100	70	Yes	No	12.6	7.5	Negative		Negative		No Growth								Necrotising granulomatous inflammation		
No			154	37	110	80	No	No	9.6	5.8	Positive	3+	Positive	Heavy	MTB grown	Pan sensitive									
No			171	51	100	80	No	No	12.75	5.5	Negative		Negative		No Growth								Necrotising granulomatous inflammation		
No			150	46	110	60	Yes	No	10.4	9.6	Positive	3+	Positive	Moderate	MTB grown	Pan sensitive									
No			161	63	120	70	No	No	9.76	6.7	Positive	3+	Positive	Heavy	MTB grown	Pan sensitive									
No			151	41	110	70	No	No	12.6	4.9	Positive	1+	Positive	Moderate	MTB grown	Pan sensitive									
No			166	40	100	70	Yes	No	13.8	5.4	Negative		Positive	Low	MTB grown	Pan sensitive									
No			156	46	110	70	No	No	11.6	5.5	Negative		Negative		MTB grown									5.2	80
No			168	47	110	80	No	No	9.7	5.7	Positive	1+	Positive	Low	MTB grown	Any resistance									
No			170	50	120	80	No	No	10.4	5.4	Positive	Scanty	Positive	Very low	MTB grown	Pan sensitive									
			154	33	100	60	No	No	11.3	5.2	Positive	1+	Positive	Moderate	MTB grown	Pan sensitive									
			175	48	100	60	No	No	14.3	5.6	Negative		Positive	Very low	MTB grown	Pan sensitive									
			171	50	110	70	No	No	10.45	0	Negative		Positive	Very low	No Growth									5.7	83
			166	53	110	80	No	No	14.7	5.6	Negative		Positive	Low											
			163	55	100	60	Yes	No	14.6	5.1	Negative		Positive	Very low	No Growth										
			179	67	110	70	No	No	11	8.7		1+	Positive	Low	MTB grown	Pan sensitive									
Yes	Yes	1 time	173	45	100	70	No	No	13.1	13	Positive	Scanty	Positive	Low	MTB grown	Pan sensitive									
			181	52	110	80	No	No	14.6	4.9	Negative		Negative											5.5	56
			164	54	130	80	Yes	No	13.9	8.9	Positive	3+	Positive	Moderate											
			172	75	110	70	No	No	16.9	5.2	Negative		Positive	Low											
			155	57	100	60	No	No	13.7	9.9	Positive	1+	Positive	Low	MTB grown	Pan sensitive									
			175	64	120	70	No	No	10.9	5	Negative		Negative											7	106
			152	36	100	60	Yes	No	10.1	5.7	Positive	2+	Positive	Moderate	MTB grown	Pan sensitive									
			159	65	110	80	No	No	12.2	10.8	Negative		Positive	Very low	No Growth										
			148	47	135	90	Yes	No	12.3	14	Positive	Scanty	Positive	Moderate	MTB grown	Pan sensitive									
			169	48	120	80	Yes	No	12.2	5	Negative		Negative		No Growth		Negative		Positive	Low	Positive		Necrotising granulomatous inflammation		
			169	44	110	80	Yes	No	14	5.8	Positive	3+	Positive	Moderate	MTB grown	Pan sensitive									
Yes	No	2 - 9 time	163	54	110	70	Yes	No	14.2	5	Positive	Scanty	Positive	Low	No Growth										
			172	45	120	80	Yes	No	12.3	5.7	Positive	3+	Positive	Moderate	MTB grown	Pan sensitive									
			180	73	130	90	No	No	15.1		Negative		Negative												
			154	40	110	70	No	No	8.4	4.8	Positive	3+	Positive	Moderate	MTB grown	Pan sensitive									
			168	41	100	70	No	No	13	5.9	Positive	2+	Positive	Heavy	MTB grown	Pan sensitive									
			160	51	100	70	No	No	17.1		Negative		Negative											5.5	117
Yes	No	1 time	172	45	110	70	Yes	No	9.6	9.3	Positive	2+	Positive	Moderate	MTB grown	Pan sensitive									
No			154	48	110	70	Yes	Yes	8.8	5.8	Negative		Positive	Very low	No Growth										
No	No	2 - 9 time	154	48	110	60	Yes	No	8.8	5.8	Negative		Positive	Very low	No Growth										
No	No		148	34	100	60	Yes	No	8	5.2	Positive	3+	Positive	Heavy	MTB grown	Pan sensitive									

pfpalbumin	ldh	ada	ph	serumprot	serumalb	serumcu	serfeth	pfa	lymneut	pfatbs	afpsev	pfhpert	fluopersev	biopxpert	biopxperts	mgitbiopsy	plufl	histopath	lungaffect	cavitation	chestscore	fev1fvcpre	fev1fvcpos	INTERPRETATION	symptom	activity	impact	totalscore	cough2m	fever2m	othsymp2m	wtgain2m	sideeff2m	othyes2m	crep2m	sputafb2m	afbsen2m	tlf2m	lungaff2m	cavit2m
																			30	Yes, 40 points	70	79	84.3		73.8	29.8	43.3	44.3	Improved	Improved	Improved	Present	No		Absent	Negative			20	Yes, 40 points
																			25	Yes, 40 points	65	84	95.3		77.6	85.8	77.8	80.2	Persistent	Persistent	Persistent	Absent	No		Absent	Positive	Scanty	Normal	25	Yes, 40 points
	3	543	43	7.41	8	4	110	566	Exudate	Lymprocytic	Negative		Negative		Positive	Low	MTB grown	Pan sensitive	Caseating granulomatous inflammation				92.51	87.78.3		72.9	74.5	44.1	58.1	Improved	Improved	Improved	Present	No		Absent	Negative		Normal		
																			35	No, 0 points	35		!5		70.4	35.5	36.2	41.7	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	No, 0 points
																			30	Yes, 40 points	70	79	57.2		73.8	62	65.7	66.8	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	25	Yes, 40 points
																			10	No, 0 points	10	82	94.1		55	17.8	22.3	26.4	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points
																			15	Yes, 40 points	55	78	81.3		52.3	72.2	57.4	67.1	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points
																			13	No, 0 points	13	81.99	81.79.3		52.4	0	11.5	14.8	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points
																			80	Yes, 40 points	120		!5		71.2	71.2	59.1	65.1	Improved	Improved	Improved	Present	No		Present	Negative		Normal	50	Yes, 40 points
																			5	Yes, 40 points	45		!5		44.7	11.9	23.7	23.6	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	2	No, 0 points
																			45	Yes, 40 points	85	82	79.3		77.6	71.3	72.2	72.9	Improved	Improved	Improved	Present	No		Present	Negative		Normal	35	Yes, 40 points
																			20	Yes, 40 points	60	80	77.1		64	62.2	52	59	Improved	Improved	Improved	Present	No		Absent	Positive	Scanty	Normal	15	No, 0 points
																			7	No, 0 points	7	84	89.3		52	38.2	40.2	43	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points
																			20	Yes, 40 points	60	82	98.1		60.2	0	37	28	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	No, 0 points
		603	35		7	3		203	Exudate	Lymprocytic	Negative		Negative		Negative		MTB grown	Pan sensitive	Caseating granulomatous inflammation				89.14	86.83.3		35.2	28	18	24.3	Improved	Improved	Improved	Present	No		Absent	Negative		Normal		
																			33	No, 0 points	33	82	90.1		42.3	49.8	38.7	48	Improved	Improved	Persistent	Present	No		Absent	Negative		Normal	15	No, 0 points
																			35	Yes, 40 points	75	78	61.		56.3	60.2	40.2	58.3	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	15	Yes, 40 points
																			15	Yes, 40 points	55	78	80.		42.3	45.6	32.8	43.2	Improved	Improved	Improved	Present	Yes	Hepatitis	Absent	Negative		Hepatitis	10	No, 0 points
																			10	Yes, 40 points	50	82	99.9.		29.8	30.2	23.6	29.2	Persistent	Improved	Improved	Present	Yes	Gastritis	Absent	Negative		Normal	5	No, 0 points
	2.4	5	37	7.33	6	3	110		Exudate	Lymprocytic	Negative								5	No, 0 points	5	79	85.		60.2	58.6	40.2	58.2	Improved	Improved	Improved	Present	Yes	Hepatitis	Absent	Negative		Normal	2	No, 0 points
																			10	No, 0 points	10	87.47	95.7 1		22.8	20.8	16.8	20.1												
																			2	No, 0 points	2	81.79	77.87.3		18.9	12.7	9.6	12.8												
																			20	Yes, 40 points	60	78	84.3		56.8	48.9	46.9	54.3	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points
																			20	Yes, 40 points	60	79	79.3		39.6	42.3	29.7	39.2	Persistent	Improved	Improved	Present	No		Absent	Negative		Normal		
			34						Exudate	Lymprocytic	Negative		Negative		Negative		No Growth		Caseating granulomatous inflammation				88.73	93.02.3		29.3	32.6	16.9	28.2	Improved	Improved	Improved	Present	No		Absent	Negative		Normal		
																			30	Yes, 40 points	70	76	80.2		46.8	55.3	34.2	49.3	Improved	Improved	Improved	Present	No		Absent	Positive	Scanty		15	No, 0 points
																			5	No, 0 points	50	81	83.1		34	32.4	22.6	29.6	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points
																			5	Yes, 40 points	45	76	84.1		38.2	40.2	28.4	38.3	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points
	3		40	7.41					Exudate	Neutrophilic	Negative		Negative		Positive	Moderate	MTB grown	Pan sensitive	Caseating granulomatous inflammation				82.1	95.3 3		37.5	28.9	16.5	28	Improved	Improved	Improved	Present	No		Absent	Negative		Normal		
																			25	No, 0 points	65	84	83.1		48	42.6	30.2	42.6	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	Yes, 40 points
																			10	No, 0 points	10	75	79.3		27.3	29.2	20.7	24.7												
																			15	No, 0 points	15	80	99.9 3		48.9	47.8	32.7	43.7												
																			20	No, 0 points	20	87.29	98.57.3		30.6	23.4	20.8	22.6												
																			35	No, 0 points	35	79	80.3		47.8	49.2	38.9	52.8	Improved	Improved	Improved	Present	No		Absent	Positive	Scanty	Normal	15	No, 0 points
																			10	No, 0 points	10	76	99.9 3		37.9	39.2	20.6	42.2	Improved	Improved	Improved	Absent	No		Absent	Negative		Normal	10	No, 0 points
																			15	No, 0 points	55	76	88.3		43.6	47.3	32.6	45.4	Improved	Improved	Improved	Absent	No		Absent	Positive	Scanty	Normal	10	No, 0 points
																		Positive	Very low			No Growth				88.17	80.91.3		28.9	22.4	23.6	25.2	Improved	Improved	Improved	Present	No		Absent	Negative		Normal		
																			10	Yes, 40 points	50	82	92.3		41.5	43.2	28.9	39.8	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points
																			10	Yes, 40 points	50	78	65.2		59.6	60.2	40.2	57.4	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	Yes, 40 points
	3.1		35	7.09					Exudate	Lymprocytic	Negative		Negative		Positive	Very low	No Growth		Caseating granulomatous inflammation				86.48	92.8 3		43.4	36.7	30.4	32.4	Improved	Persistent	Improved	Present	No		Absent	Negative		Normal		
																			30	Yes, 40 points	70	79	86.1		64	54	52	55												
																			30	No, 0 points	30	84	96.3		67	48.7	32.7	50.2												
																			80	Yes, 40 points	120	95	96.3		59	67	48	55												
																			20	Yes, 40 points	60	84	91.3		75	99	54	71	Improved	Improved	Improved	Present	Yes	Hepatitis	Absent	Negative		Hepatitis	20	Yes, 40 points

chestscore2m	fev1fvcpre2m	fev1fvcpre2m	fev1fvcpost2m	interp2m	dlcocvapre2m	dlcocvapre2m	dlcocvaprepre2m	dlcointer	tlchepreptre2m	interlung	symp2m	activity2m	impact2m	total2m	attneg2m	cough6m	fever6m	othsym6m	wtgain6m	sideeff6m	effyes6m	crep6m	squafb6m	sevposi6m	tlf6m	lungaff6m	cavit6m	chestsc6m	fev1fvcpre6m	fev1fvcpre6m	fev1fvcpost6m	interp6m	dlcointer6m	tlchepreptre6m	lungint6m	symscore6m
60		81.59	80.46	83.68	Restriction	1.4	1.69	120.5	Nomal	86.5	Abnormal	34.2	62.9	26	18.5		Improved	Improved	Improved	Present	No		Absent	Negative			5	No, 0 points	5	81.59	82.15	80.6	Normal	Nomal		86	Nomal	17.4
65		88.34	90.46	93	Restriction	1.72	2.25	131.2	Nomal	73	Abnormal	47.5	66.9	60.5	60.3	HRE	Persistent	Improved	Improved	Present	No		Absent	Negative		Normal	10	Yes, 40 points	50	88.34	91.44	95.24	Restriction	Nomal		64	Abnormal	40.9
		82.3	87.5	88.9		1.38	2	150		67.01		21.5	41.8	16.6	25.7	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal				82.24	80.56	83.86	Restriction	Nomal		68	Abnormal	7.7
20		86.42	94.28	109.1	Restriction	1.8	2.13	118	Nomal	74	Nomal	31	17.9	15.2	18.7	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points	10	91.89	96.66	95.96	Restriction	Nomal		134	Abnormal	10.5
65		80.21	75	74	Obstruction	0	0	0	Abnormal	50		43	65.5	36.5	46.4	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	Yes, 40 points	50	80	76.6	73.9	Obstruction	Abnormal		54	Abnormal	15.6
5		87.98	97.61	91.12	Nomal	1.5	2.2	149.5	Nomal	103.6	Abnormal	18.4	0	1.6	3.9	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	0	87.72	94.36	95.69	Nomal	Nomal		96.3	Nomal	63.2
10		78.33	81.23	80.9	Restriction	1.71	1.58	92.3	Nomal	79.2	Nomal	35.3	43	25.2	32	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	2	No, 0 points	2	78.3	76.5	79.19	Restriction	Nomal		69.4	Abnormal	20.4
10		81.94	90.33	94	Restriction	1.71	2.81	164	Nomal	67	Abnormal	24.8	0	0	4.1	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	82.96	88.88	92.04	Restriction	Nomal		66.99	Abnormal	6.3
90		83.76	78.41	78.78	Restriction	1.72	2.29	133.6	Nomal	66	Abnormal	34.3	12.6	15.4	17.7	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	No, 0 points	20	83.46	77.05	79	Restriction	Nomal		59.4	Abnormal	15.1
2		80.7	74.6	79	Restriction	1.4	2.34	167.1	Nomal	72.06	Abnormal	6.3	0	5.3	3.8	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	0	84.26	74.31	76.29		Nomal		70.3	Nomal	6.3
75		85.75	76.6	78.07	Restriction	1.72	2.6	151.6	Nomal	67.6		51.2	35.5	33.7	37.1	HRE	Improved	Improved	Improved	Present	Yes		Present	Negative		Normal	10	No, 0 points	10	88.88	84.88	82.6	Restriction	Nomal		87.1	Nomal	25.3
15												46	28.2	24.7	33	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	2	No, 0 points	2	82.91	79.25	81.27	Nomal	Nomal		84.4	Nomal	19
5		99.09	81.59	90.79	Restriction	1.72	3.04	177	Nomal	63	Abnormal	36.2	24.6	20.2	27	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	2	No, 0 points	2	88.09	86.58	84.19	Restriction	Nomal		72.3	Nomal	18.2
20		88.53	90.28	88.08	Nomal	1.74	2.6	149.6	Nomal	96.8	Nomal	23	0	10	8.9	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	93.6	90.7	89.17	Nomal	Nomal		97.11	Nomal	3
		88.83	81.2	89.44		1.72	2.17	126.6	Nomal	81.5	Nomal	18.6	22.6	10.2	16	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal				88.88	87.55	80.35	Restriction	Nomal		75	Abnormal	16.2
15		88.39	81.35	84.92		1.62	3.32	204.9	Nomal	76.5		28.6	29.4	17.8	26.2	HRE	Improved	Improved	Persistent	Present	No		Absent	Negative		Normal	5	No, 0 points	5	88.39	84.2	87.99		Nomal		85.4	Nomal	17.3
55																	Persistent	Persistent	Persistent	Absent	No			Positive			15	Yes, 40 points	55									
10		79.22	78.44	84.84		1.71	2	116.8		70	Nomal	28.3	22.4	16.2	24.3		Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	79.28	76.34	79.37	Restriction	Nomal		69.3	Abnormal	18.2
5		90.9	96.27	96.57	Nomal	1.4	2.55	182.1	Nomal	80.8	Nomal	16.8	12.8	10.2	14.8	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	0	87.81	95	96	Nomal	Nomal		80.8	Nomal	13.6
2		79.44	74.55	81.06		1.33	2.12	160.1	Nomal	71.1	Abnormal	23	20.8	16.9	18	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	0	79.41	68.38	73.17		Nomal		76.8	Nomal	13.2
																	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	0	89.9	83.33	83.62	Nomal	Nomal		98.07	Nomal	12
																	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	0	85.67	86.5	86.41	Nomal	Nomal		86.3	Nomal	11.1
10		80.16	76.87	81.32	Restriction	1.35	2	150.8	Nomal	55.09	Abnormal	28	30.2	26.7	28.9	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	80.16	73.2	78.48	Restriction	Nomal		55.5	Abnormal	16.7
																HRE																				
		88.73	89.43	93.12	Restriction	1.32	2.82	214.7	Nomal	54.9	Abnormal	18.6	20.2	15.6	16.8	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal				88.73	93.28	93.46		Nomal		63	Abnormal	14.8
15		78.07	78.02	80.08	Nomal	1.2	2.09	178.8	Nomal	88.6	Nomal	22.7	20.9	19.6	24.6	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	2	No, 0 points	2	82.18	77.87	77.4	Nomal	Nomal		69.1	Nomal	12.6
0		85.61	79.88	81.64	Nomal	1.44	2.6	180	Nomal	83.5	Nomal	20.9	18.6	12.4	19.2	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	0	84.76	80.6	83.46	Nomal	Nomal		74.8	Nomal	12.6
5		77.58	78.62	80.53	Restriction	1.09	2.1	192.6	Nomal	87	Nomal	20.2	21.6	16.7	19.5		Improved	Improved	Improved	Absent	No		Absent	Negative		Normal	5	No, 0 points	5	77.58	78.62	80.53	Nomal	Nomal		108.1	Nomal	18.6
		82.13	91.46	94.99	Nomal	1.39	2.07	148.9	Nomal	99.6		18	20.3	12.9	16.8	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal				82.13	91.45	94.99	Nomal	Nomal		99.6	Nomal	14.3
60		90.21	90.74	84.48	Restriction	1.72	1.84	107.4	Abnormal	57.9	Abnormal	32	28.9	20.3	28.9	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	Yes, 40 points	45	90.21	82.26	85.72	Restriction	Abnormal		68.9	Abnormal	16.8
																	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	0	78.05	71.35	70.7	Restriction	Nomal		74.57	Abnormal	18
																	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points	10	92.6	96.29	96.61	Nomal	Nomal		94.64	Nomal	18.9
15		87.9	78.07	76.35	Restriction	1.39	1.75	126.9	Nomal	68.46	Abnormal	30.2	32.4	20	31		Improved	Improved	Improved	Present	No		Absent	Positive		Normal	10	No, 0 points	10	81.74	76.59	78.44	Restriction	Nomal		69.5	Nomal	16.4
10		78.1	78.84	78.85	Restriction	1.21	1.88	155.2	Nomal	62.62	Abnormal	30.9	31.6	18.9	32.2	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	84.7	82.6	80.17	Nomal	Nomal		82.03	Nomal	8.9
50																	Improved	Improved	Improved	Present	No		Present	Negative		Normal	25	No, 0 points	25	76.2	88	116.5	Restriction	Nomal		55.44	Abnormal	22.9
		86.95	80	82.01	Restriction	1.32	2.88	217.4	Abnormal	61.2	Abnormal	22.6	23.4	19.9	25.3	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal				87.93	78.62	81.82	Restriction	Nomal		63	Abnormal	12.9
5						1.69	2.11	124.9	Nomal	83.77	Nomal	15.6	16.2	13.2	15.5	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	27	84.88	90.39	93.89	Nomal	Nomal		84.01	Nomal	9.8
45		87.31	54.22	56.05	Restriction	1.37	1.78	129.9	Nomal	68.47	Abnormal	30.4	26.7	22.4	31.4	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	Yes, 40 points	45	80.79	56.36	60.31	Obstruction	Nomal		70	Nomal	28.9
		86.22	69.4	77.45	Restriction	1.74	2.57	147.7	Nomal	62.9	Abnormal	21.4	22.5	19.8	24.6	HRE	Improved	Improved	Improved	Present	No		Absent	Negative		Normal				86.22	74.7	77.64	Restriction	Nomal		68.4	Abnormal	16.8
																	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	87.67	93.86	94.3	Restriction	Nomal		76.5	Abnormal	23.4

activity6m	impact6m	total6m	cure	fev1_post_per	age_r	bmi_r	fev1_6mpost_per	fev1_b_per	fev1_2m_postper	fev1_6m_postper	hb_r	diabetes	fev1fvc_b_per	fev1fvc_2m_per	fev1fvc_6m_per	tlc_2m_per	tlc_6m_per
6.2	3.8	6.8	Yes	Normal	30-50	Low	Normal	Normal	Normal	Normal	Moderate	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Normal
30.5	26.5	30.1	Yes	Moderate	<30	Low	Moderate	Moderate	Moderate	Moderate	Severe	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
5.2	11.5	8.8	Yes	Mild	30-50	Overweight	Mild	Moderate	Mild	Mild	Normal	Pre-diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
5.9	5.9	6.7	Yes	Mild	<30	Low	Mild		Mild	Mild	Moderate	Normal		Normal/Restriction	Normal/Restriction	Mild	Normal
59.5	22.5	32.6	Yes	Severe	>50	Obese	Severe	Severe	Severe	Severe	Moderate	Normal	Obstruction	Normal/Restriction	Normal/Restriction	Moderate	Moderate
0	1.6	1.9	Yes	Normal	<30	Normal	Normal	Normal	Normal	Normal	Normal	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Normal
12.5	7.7	11.2	Yes	Mild	>50	Low	Mild	Mild	Moderate	Mild	Moderate	Pre-diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
0	0	1	Yes	Mild	30-50	Normal	Mild	Moderate	Mild	Mild	Normal	Diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
0	7.5	6.5	Yes	Moderate	30-50	Low	Moderate		Moderate	Moderate	Moderate	Pre-diabetes		Normal/Restriction	Normal/Restriction	Mild	Moderate
0	0	1	Yes	Normal	30-50	Low	Normal		Normal	Normal	Mild	Normal		Normal/Restriction	Normal/Restriction	Mild	Mild
17.4	5.2	12.2	Yes	Normal	30-50	Normal	Normal	Severe	Moderate	Normal	Moderate	Diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Normal
12	4.2	11.4	Yes	Normal	30-50	Normal	Normal	Normal		Normal	Moderate	Diabetes	Normal/Restriction		Normal/Restriction		Normal
10.2	8.2	12	Yes	Mild	<30	Normal	Mild	Mild	Normal	Mild	Normal	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
0	0	0.4	Yes	Normal	<30	Low	Normal	Normal	Normal	Normal	Normal	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Normal
12.2	8.6	11.2	Yes	Moderate	<30	Low	Moderate	Mild	Mild	Moderate	Mild	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Mild
18.2	12.2	15	Yes	Normal	<30	Low	Normal	Normal	Normal	Normal	Moderate	Pre-diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Normal
			Lost to followup		30-50	Low		Severe			Moderate	Normal	Obstruction				
16.8	10.2	13.2	Yes	Moderate	>50	Low	Moderate	Mild	Moderate	Moderate	Mild	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
10.7	6.8	10.3	Yes	Normal	<30	Low	Normal	Normal	Normal	Normal	Normal	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Normal
10.8	6.2	11.2	Yes	Normal	>50	Low	Normal	Moderate	Normal	Normal	Moderate	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
6.8	0	5.6	Yes	Normal	<30	Normal	Normal	Normal		Normal	Normal	Normal	Normal/Restriction		Normal/Restriction		Normal
10.8	4.7	6.7	Yes	Normal	30-50	Normal	Normal	Mild		Normal	Normal	Normal	Normal/Restriction		Normal/Restriction		Normal
17.2	8.9	12.6	Yes	Mild	>50	Normal	Mild	Moderate	Mild	Mild	Mild	Diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Moderate	Moderate
			Lost to followup		30-50	Low		Moderate			Normal	Diabetes	Normal/Restriction				
15.2	4.6	11.5	Yes	Moderate	<30	Low	Moderate	Moderate	Moderate	Moderate	Normal	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Moderate	Mild
11	8.5	11.2	Yes	Moderate	<30	Normal	Moderate	Moderate	Moderate	Moderate	Normal	Diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Normal
8.9	5.8	10.2	Yes	Normal	30-50	Obese	Normal	Normal	Normal	Normal	Normal	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Mild
13.4	8.9	13.6	Yes	Normal	>50	Overweight	Normal	Normal	Normal	Normal	Normal	Diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Normal
12	8.4	11.6	Yes	Normal	30-50	Normal	Normal	Moderate	Normal	Normal	Moderate	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Normal	Normal
20.2	11.2	16.4	Yes	Moderate	<30	Low	Moderate	Severe	Severe	Moderate	Moderate	Pre-diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Moderate	Mild
19.2	12.3	16.7	Yes	Moderate	>50	Obese	Moderate	Moderate		Moderate	Mild	Diabetes	Normal/Restriction		Normal/Restriction		Mild
			Lost to followup		30-50	Normal		Moderate			Normal	Diabetes	Normal/Restriction				
16.7	7.8	12.7	Yes	Normal	<30	Low	Normal	Normal		Normal	Mild	Normal	Normal/Restriction		Normal/Restriction		Normal
18.2	12.4	14.8	Yes	Moderate	30-50	Low	Moderate	Moderate	Moderate	Moderate	Normal	Pre-diabetes	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
10.2	5.4	11.2	Yes	Normal	>50	Normal	Normal	Moderate	Mild	Normal	Normal	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Normal
21.9	13.8	17.8	Yes	Moderate	>50	Low	Moderate	Severe		Moderate	Mild	Pre-diabetes	Normal/Restriction		Normal/Restriction		Moderate
12.3	9.2	10.7	Yes	Mild	<30	Normal	Mild	Mild	Moderate	Mild	Normal		Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
10	4.6	8.9	Yes	Normal	30-50	Low	Normal	Normal	Normal	Normal	Moderate	Normal	Normal/Restriction		Normal/Restriction	Normal	Normal
30.2	29.2	35.4	Yes	Severe	30-50	Low	Severe	Moderate	Severe	Severe	Normal	Pre-diabetes	Obstruction	Obstruction	Obstruction	Mild	Mild
12.8	10.7	11.1	Yes	Moderate	<30	Normal	Moderate	Moderate	Moderate	Moderate	Normal		Normal/Restriction	Normal/Restriction	Normal/Restriction	Mild	Mild
			Lost to followup		30-50	Low		Normal			Moderate	Diabetes	Normal/Restriction				
18.6	10.2	16.7	Yes	Mild	<30	Normal	Mild	Moderate		Mild	Moderate	Pre-diabetes	Normal/Restriction		Normal/Restriction		Mild
			Lost to followup		<30	Normal		Severe			Moderate	Pre-diabetes	Normal/Restriction				
21.3	14.7	20.9	Yes	Moderate	<30	Low	Moderate	Severe	Moderate	Moderate	Moderate	Normal	Normal/Restriction	Normal/Restriction	Normal/Restriction	Moderate	Moderate

45	270475H	SAMIR BAURI	East	43	Male	20.7	Pulmonary	Yes	3	Yes	Yes	Yes	Yes	No	No	Former	Cigarette	10	Yes	No	No	No	No		
46	330205H	SUDESHNA GHOSH	East	31	Female	12.9	Pulmonary	Yes	3	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
47	067833G	PERIYASAMY	South	46	Male	17.2	Pulmonary	Yes	2	No	Yes	Yes	Yes	No	No	Current	Cigarette	5	Yes	No	No	No	No		
48	340771H	POONGAVANAM	South	66	Male	16.4	Pulmonary	Yes	1	No	Yes	Yes	Yes	Yes	No	Current	Beedi	10	No	No	No	No	No		
49	343801H	ISHITA CHAKRABARTHY	East	25	Female	13.4	Pulmonary	Yes	4	Yes	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
50	644588G	MANAS KUMAR	East	33	Male	21	Pulmonary	Yes	1	No	No	Yes	Yes	No	No	Current	Cigarette	7	No	No	No	No	No		
51	334979H	PRAMETH NATH SARKAR	East	67	Male	26.4	Pulmonary	Yes	1	Yes	No	No	No	No	No	Former	Cigarette	20	Yes	No	No	No	No		
52	354273H	GIRI	South	44	Male	20.3	Pulmonary	Yes	1	No	Yes	Yes	Yes	No	No	Never			Yes	No	No	No	No		
53	188570H	TAMILSELVAN	South	41	Male	17.3	Pulmonary	Yes	2	No	Yes	Yes	Yes	Yes	No	Current	Cigarette	15	Yes	No	No	No	No		
54	894660D	SAMPATH	South	29	Male	16.1	Pulmonary	Yes	2	Yes	No	No	No	Yes	No	Never			No	No	No	No	No		
55	339911F	PANKAJ DEY	East	45	Male	24.8	Pulmonary	Yes	3	Yes	Yes	Yes	Yes	No	No	Current	Cigarette	8	No	No	No	No	No		
56	344800H	ABRAR AHMED	South	19	Male	17.2	Pulmonary	Yes	1	No	No	No	No	No	No	Never			No	No	No	No	No		
57	766723D	MALLIKA	South	65	Female	27.3	Pulmonary	Yes	5	Yes	No	No	No	Yes	No	Never			Yes	No	No	No	No		
58	393182H	NAVEED	South	29	Male	18.8	Pulmonary	Yes	2	No	Yes	Yes	Yes	Yes	Yes	Current	Cigarette	3	No	No	No	No	No		
59	373414H	MUN MUN KUMARI	East	24	Female	21.6	Pulmonary	Yes	24	Yes	Yes	Yes	No	Yes	No	Never			No	No	No	No	No		
60	335240H	SRIBASH	East	49	Male	17.2	Pulmonary	Yes	2	Yes	Yes	Yes	Yes	Yes	No	Current	Cigarette	10	No	No	No	No	No		
61	398549H	BRAMANANTHACHARY	South	55	Male	14.2	Pulmonary	Yes	12	No	No	No	No	Yes	No	Current	Cigarette	10	No	No	No	No	No		
62	403373H	RASHMI RANJAN	East	43	Male	19.8	Pulmonary	Yes	2	No	Yes	Yes	Yes	Yes	No	Never			Yes	No	No	No	No		
63	567905H	SINDHU	South	19	Female	18.8	Pulmonary	Yes	1	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
64	425683H	MOHAMED ALI	Bangladesh	64	Male	26.4	Pulmonary	Yes	3	No	Yes	Yes	Yes	No	No	Former	Cigarette	8	Yes	No	No	No	No		
65	443381H	KRISHNA MONDAL	East	42	Male	23.6	Pulmonary	Yes	4	Yes	Yes	Yes	Yes	Yes	No	Former	Cigarette	6	No	No	No	No	No		
66	952378C	SHANKAR	South	44	Male	18.6	Pulmonary	Yes	2	No	Yes	Yes	Yes	No	No	Current	Cigarette	8	No	No	No	No	No		
67	445479H	MOHITOSH	East	38	Male	21.5	Pulmonary	Yes	12	Yes	No	No	No	No	No	Never			No	No	No	No	Yes		Pulmonary
68	477031H	VANAM SHYAMALA	South	34	Female	17.1	Pulmonary	Yes	1	No	No	No	No	Yes	Yes	Never			No	No	No	No	No		
69	510567G	DHAKSHNAMOORTHY	South	47	Male	19.5	Pulmonary	Yes	5	Yes	No	No	Yes	Yes	Yes	Former	Cigarette	20	Yes	No	No	No	No		
70	478940H	MANOGARAN	South	37	Male	19.3	Pulmonary	Yes	5	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
71	403069D	SASIKALA	South	59	Female	27.5	Pulmonary	Yes	1	No	Yes	Yes	Yes	Yes	Yes	Never			Yes	No	No	No	No		
72	441869H	SIVACHANDRAN	South	28	Male	19.5	Pulmonary	Yes	4	No	No	Yes	Yes	No	No	Never			No	No	No	No	No		
73	587762C	MOGHEL AHMED	South	42	Male	16.9	Pulmonary	Yes	2	Yes	Yes	Yes	Yes	No	No	Never			No	No	No	No	Yes		1 Pulmonary
74	457385H	KUNAL BARMEN	East	18	Male	18	Pulmonary	Yes	2	Yes	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
75	099950H	SOMA BISWAS	North	42	Female	24.1	Pulmonary	No		No	No	No	No	No	No	Never			No	No	No	No	No		
76	420459H	NIRMAL KUMAR	South	44	Male	16.3	Pulmonary	Yes	2	No	Yes	Yes	Yes	Yes	No	Former	Cigarette	12	No	No	No	No	Yes		1
77	425280H	SHEIKH MENNAN	Bangladesh	50	Male	22	Pulmonary	Yes	24	No	No	Yes	No	Yes	No	Never			Yes	No	No	No	No		
78	036244B	RENUKA	South	42	Female	19.6	Pulmonary	Yes	6	No	No	No	No	No	No	Never			No	No	No	No	No		
79	506688G	DURAIRAJ	South	66	Male	21.8	Pulmonary	Yes	1	No	Yes	Yes	Yes	No	No	Never			Yes	No	No	No	No		
80	515655H	SANDIP SARDAR	East	40	Male	15	Pulmonary	Yes	1	No	No	Yes	Yes	No	No	Former	Cigarette	11	No	No	No	No	Yes		1 Pulmonary
81	104499H	MANIL RAI	East	38	Male	25.8	Pulmonary	Yes	5	No	No	No	No	No	No	Former	Cigarette	5	No	No	No	No	No		
82	561031F	GAURI	South	22	Female	18	pleura	Yes	1	No	No	No	No	No	Yes	Never			No	No	No	No	No		
83	895460F	SIVANATH	South	38	Male	16.2	Pulmonary	Yes	1	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
84	516711H	SK ATAUR RAHMAN	Bangladesh	50	Male	14	Pulmonary	Yes	2	No	Yes	Yes	Yes	Yes	Yes	Never			Yes	No	No	No	No		
85	246534H	SAILESH KUMAR	East	43	Male	19.8	Pulmonary	Yes	1	No	Yes	Yes	Yes	No	No	Former			No	No	No	No	No		
86	498848H	SANJIT DAS	East	30	Male	24.2	Pulmonary	Yes	3	Yes	No	No	No	Yes	No	Current	Cigarette	3	No	No	No	No	No		
87	483109H	MOHAN	South	59	Male	15.8	Pulmonary	Yes	12	Yes	Yes	Yes	Yes	No	No	Current	Cigarette	7	No	No	No	No	Yes		1 Pulmonary
88	481465H	SASHI PRADHAN	East	41	Female	18.6	Pulmonary	Yes	2	No	No	No	No	Yes	No	Never			No	No	No	No	No		
89	562592H	SHANTHI	South	61	Female	17.1	Pulmonary	No		Yes	No	No	No	Yes	No	Never			Yes	No	No	No	No		
90	524722H	RUBINI	South	21	Female	19.5	pleura	Yes	1	No	Yes	Yes	Yes	Yes	Yes	Never			No	No	No	No	No		
91	520540H	THANDAPANI	North	19	Male	18.7	Pulmonary	Yes	3	No	Yes	Yes	Yes	No	No	Never			No	No	No	No	No		
92	544485f	Krishnamma	South	45	Female	18.7	Pulmonary	Yes	2	No	Yes	No	Yes	No	No	Never			No	No	No	No	No		

No	No		176	64	120	80	Yes	Yes	13.1	8.2	Negative		Negative						Positive	Low	Positive	Very low	Necrotising granulomatous inflammation																	
			150	29	100	60	Yes	No	10.2	5.3	Negative		Positive	Low	MTB grown	Pan sensitive																								
			169	49	130	70	Yes	Yes	11.2	11	Positive	3+	Positive	Moderate	MTB grown	Pan sensitive																								
No			158	41	120	70	Yes	Yes	11	6.8	Positive	2+	Positive	Low	MTB grown	Pan sensitive																								
No	No		159	34	100	60			7.7	5.2	Positive	2+	Positive	Low	MTB grown	Pan sensitive																								
			176	65	120	70	No	No	10.2	5.2	Positive	1+	Positive	Low	MTB grown	Pan sensitive																								
			172	78	130	70	No	No	12.8	7.7	Negative		Positive	Low	MTB grown	Pan sensitive																								
			163	54	110	70	No	No	14.3	11	Positive	2+	Positive	Heavy	MTB grown	Pan sensitive																								
			163	46	120	70	Yes	No	11.5	14	Negative		Positive	Low	MTB grown	Pan sensitive																								
			185	55	110	70	No	No	14.4	5.7	Positive	Scanty	Positive	Low	MTB grown	Pan sensitive																								
			163	661	110	70			11.7	6.1	Positive	2+	Positive	Moderate	MTB grown	Pan sensitive																								
			179	55			No	No	11.2	5.4	Positive	2+	Positive	Moderate	MTB grown	Pan sensitive																								
			160	70	110	70			13.9	8.5	Negative		Positive	Low	MTB grown	Any resistance																								
			183	63	110	70	No	No	12.4	5.4	Positive	3+	Positive	Heavy	MTB grown	Pan sensitive																								
			158	54	110	70	Yes	Yes	11.1	4.7	Positive	Scanty	Positive	Low	MTB grown	Pan sensitive																								
			167	48	120	70	No	No	12.3	6.2	Positive	1+	Positive	Low	MTB grown	Any resistance																								
			174	43	130	70			12.7	5.4	Positive	1+	Positive	Moderate	MTB grown	Pan sensitive																								
			174	60	110	70	No	No	12.6	10	Negative		Positive	Low	MTB grown	Pan sensitive																								
			153	44	106	70	Yes	No	9.6	5.5	Positive	3+	Positive	Moderate	MTB grown	Pan sensitive																								
			158	66	120	60	Yes	Yes	9.2	9.5	Positive	Scanty	Positive	Low	MTB grown	Pan sensitive																								
			158	59	124	60	Yes	No	13.2	6.4	Positive	2+	Positive	Moderate	MTB grown	Pan sensitive																								
			169	43	110	70	No	No	11.2	5.4	Positive	Scanty	Positive	Low	MTB grown	Pan sensitive																								
Yes	Yes	1 time	178	68	110	70	No	No	12.54	0.9	Negative		Positive	Low	MTB grown	Pan sensitive																								
			151	39	118	60	No	No	11.5	5.3	Negative		Positive	Very low	No Growth																									
			160	50	140	90	Yes	No	14.7	5.4	Positive	2+	Positive	Moderate	MTB grown	Pan sensitive																								
			172	57	120	86	Yes	No	13.8	6.3	Positive	3+	Positive	Moderate	MTB grown	Pan sensitive																								
			165	75	126	80	Yes	Yes	12.3	8.2	Positive	2+	Positive	Moderate	MTB grown	Pan sensitive																								
			177	61	120	70	No	No	11.3	4.5	Negative		Negative		MTB grown								Necrotising granulomatous inflammation																	
Yes	Yes	1 time	148	37	108	60	No	No	13.4	5.4	Negative		Positive	Very low	MTB grown	Pan sensitive																								
			173	54	120	70	No	No	12.8		Positive	3+	Positive	Heavy	MTB grown	Pan sensitive																								
			151	55	120	76			9.6	5.6	Negative		Negative		MTB grown	Pan sensitive					Negative		Necrotising granulomatous inflammation																	
Yes	No	1 time	170	47	110	70	Yes	Yes	10.3	6	Negative		Negative		MTB grown	Pan sensitive			Positive	Low																				
			172	65	126	80	Yes	No	13.9	12	Positive	Scanty	Positive	Heavy	MTB grown	Pan sensitive																								
			158	49	110	60	Yes	No	11.8	5.4	Positive	Scanty	Positive	Low	MTB grown	Pan sensitive																								
			163	58	130	70	No	No	13.2	9.9	Positive	Scanty	Positive	Low	MTB grown	Pan sensitive																								
Yes	Yes	1 time	173	45	110	60	No	No	8.2	4.1	Negative		Positive	Very low	No Growth																									
			167	62	110	70	No	No	12.4		Positive	2+	Positive	Low	MTB grown	Pan sensitive																								
			147	39	114	60	No	No	12		Negative		Negative											5.7	65	3	373	25	7.4	7	3.7	86	373	Exudate	Lympocytic	Negative		Negative		
			163	43	128	70	Yes	Yes	9	6	Positive	3+	Positive	Moderate	MTB grown	Pan sensitive																								
			165	38	130	70	Yes	Yes	10.3	11.3	Positive	2+	Positive	Moderate	No Growth																									
			162	52	110	60	No	No	11.9	5.9	Negative		Positive	Low	MTB grown	Pan sensitive																								
			170	70	110	70	No	No	14.5	4.9	Negative		Negative		No Growth						Positive	Low	Necrotising granulomatous inflammation																	
Yes	No	1 time	178	50	122	70	Yes	Yes	9.3	5.5	Positive	Scanty	Positive	Moderate	MTB grown	Pan sensitive																								
			152	43	128	86	No	No	9.6	5.1	Positive	1+	Positive	Moderate	MTB grown	Pan sensitive																								
			145	36	100	70	Yes	Yes	12.2	12.5	Positive	1+	Positive	Low	MTB grown	Pan sensitive																								
			153	45	104	60	No	No	10.9	5.9	Negative		Negative											5	57	2.4	581	42	7.08	8.3	4	127	320	Exudate	Lympocytic	Negative		Negative		Negative
			165	51	116	80	Yes	No	14.9	5.6	Positive	1+	Positive	Moderate	MTB grown	Pan sensitive																								
			160	48	130	70			11.4	4.9	Negative		Negative		No Growth		Negative		Positive	Very low	Negative		Necrotising granulomatous inflammation																	

				5	No, 0 points	5	82.72	71.16	3	57	49	69	61	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points	10	0.79	74.89	0.75	Restriction	1.42	2.11	148	Normal	75.62	Normal
				10	No, 0 points	10	83	99	3	39	6	28	24.2	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	85.4	90.4	89.6	Restriction	1.72	2.23	129.6	Normal	60.8	Abnormal
				30	Yes, 40 points	70	77	81	1	54	60	56	57	Improved	Improved	Improved	Present	No		Present	Positive	Scanty	Normal	20	No, 0 points	20	79.82	75.86	76.5	Normal	1.32	1.75	132.1	Normal	77.8	Abnormal
				45	No, 0 points	45	75	99.9	3	63	72	74	72	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points	10	79.27	66.04	66.99	Obstruction	1.25	1.13	90.5	Normal	72.3	Abnormal
				15	No, 0 points	15	84	83	3	39	0	41	29	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points	10	88.71	93.29	93.6	Restriction	1.72	2.15	125.5	Normal	79	Abnormal
				5	No, 0 points	45	81	95	1	46	0	26	21	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	85.42	84.03	86.3	Restriction	1.4	2.31	165.1	Normal	71.9	Abnormal
				5	No, 0 points	5	75	93	3	34	0	5.9	8.8	Improved	Improved	Persistent	Absent	No		Absent	Negative		Normal	2	No, 0 points	2	76.31	79.38	79.68		1.28	1.85	144.3	Normal	84	Normal
				40	Yes, 40 points	40	79	87	3	48	0	49	34	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	25	No, 0 points	25	82.14	78.54	78.41	Restriction	1.43	2.38	166.8	Normal	66.9	Abnormal
				20	Yes, 40 points	60	78	83	3	62	60	74	67	Improved	Improved	Improved	Present	No		Present	Negative		Normal	10	Yes, 40 points	50	80.35	83.66	104.1	Restriction	1.34	1.92	142.7	Normal	99	Normal
				10	Yes, 40 points	10	82	90	1	34	30	43	37	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	82.18	83	88.4	Normal	1.26	2	152	Normal	10.5	Normal
				30	Yes, 40 points	80	79	77	.	53	49	61	56																							
				25	Yes, 40 points	65	83.19	84.37	1	34	0	9.2	11	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points	10	87	76	84	Restriction	1.41	2.73	208.2	Normal	78	Abnormal
				10	No, 0 points	10	76	98	3	59	86	58	68	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	76.5	96.59	96.48	Restriction	1.71	1.68	97.9	Normal	79.04	Abnormal
				25	Yes, 40 points	65	82	90	3	62	74	46	58	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	No, 0 points	20	86.33	83.12	87.78		1.3	2.5	191	Normal	65.5	
				5	No, 0 points	5	84	83	.	59	61	60	60	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	2	No, 0 points	2	88.75	79.3	78.56		1.72	2.06	170.2		80.7	Normal
				35	Yes, 40 points	75	78	80	3	59	87	30	54	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	15	Yes, 40 points	55	80.85	73.7	78.1	Restriction	1.36	1.81	132.5	Normal	61.6	Abnormal
				25	Yes, 40 points	65	79	60.63	2	64	38	43	45	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	Yes, 40 points	60	79.29	55.64	66.54		1.34	1.33	99.7	Normal	74.1	Abnormal
				5	Yes, 40 points	45	78	99	1	50	42	42	44	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	81.07	88.3	85.2		1.36	2.24	164.7	Normal	87.2	Normal
				20	No, 0 points	20	84.3	88.9	3	43.6	46.8	34.8	43.9	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	90.73	82.13	90.5	Restriction	1.72	2.53	147	Normal	72.1	Abnormal
				30	No, 0 points	30	75	85	3	46	23	57	44																							
				10	No, 0 points	10	79	86	3	62	47.3	26.4	39.5	Improved	Improved	Improved	Present	No		Absent	Positive	2+	Normal	5	No, 0 points	5	82.23	80.69	83.08		1.46	2.21	150.7	Normal	76.4	Abnormal
				70	Yes, 40 points	110	79	70	3	62	36.3	15.3	30.6	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	30	No, 0 points	30	82.63	72.5	72.47	Normal	1.27	1.75	137	Normal	83.9	Normal
				5	No, 0 points	5	80	85	3	24.2	0	17.5	12.7	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	2	No, 0 points	2	0.81	0.88	0.84	Normal	1.72	2.23	129.6	Normal	73.5	Abnormal
				5	No, 0 points	5	83	96	3	26	36	16	25	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	2	No, 0 points	2	86.27	95.76	96.95	Restriction	1.72	2.23	130	Normal	73.5	Abnormal
				15	No, 0 points	15	78	76	3	54	42	78	62	Improved	Improved	Improved	Present	No		Absent	Positive	Scanty	Normal	5	No, 0 points	5	0.78	76.22	0.78	Restriction	1.4	2.46	175.7	Normal	73.85	Abnormal
				25	Yes, 40 points	65	80	93	1	45	12	29	26	Improved	Improved	Improved	Present	No		Absent	Positive	Scanty	Normal	20	Yes, 40 points	60	85.64	85.14	84.44	Normal	1.47	2.73	185.7	Normal	80.7	Normal
				20	Yes, 40 points	60	78	82	3	74	30	59	52	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	No, 0 points	20	77.24	74	74.48	Restriction	1.71	1.95	114	Normal	76	Abnormal
				20	No, 0 points	20	86.75	87.6	.	34	0	25	19	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	No, 0 points	20										
				10	No, 0 points	10	79	76	1	64	25	68	53	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	5	No, 0 points	5	82.09	78.6	85.25		1.51	1.95	128.9	Normal	90.5	Normal
				50	Yes, 40 points	90	93	88	.	43	25	33	32																							
				5	No, 0 points	5	84.19	86.2	3	65	0	0	12	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	2	No, 0 points	2	83.89	81.69	84.71	Normal	1.72	1.82	106.1	Normal	87.1	Normal
				60	No, 0 points	80	82.01	74.74	.	58	36	38	41	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	100	Yes, 40 points	140										
				15	Yes, 40 points	55	78	72	3	74	31	35	41	Improved	Improved	Improved	Present	No		Absent	Positive	Scanty	Normal	15	No, 0 points	15	0.78	75	0.74							
				15	Yes, 40 points	55	81	99.9	3	32.3	6.2	48.2	33.8	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points	10	83.6	70.07	70.41		1.72	2.66	155.3	Normal	77.9	Abnormal
				20	No, 0 points	20	75	84	3	48	38	44.7	42.8	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	No, 0 points	10	76.44	81.29	82.19	Restriction	1.09	1.7	156.1	Normal	71	Abnormal
				10	No, 0 points	10	80	68	2	45.9	0	48.3	33																							
				25	No, 0 points	25	80	90	3	24.3	0	11	9.4	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	No, 0 points	20	85.2	87.8	88.6	Restriction	1.51	2.78	183.5	Normal	68	Abnormal
	MTB grown	Any resistance	Caseating granulomatous inflammation				89.81	89.64	3	40.2	42.8	38.7	40.2	Improved	Improved	Improved	Present	No		Absent	Negative		Normal				89.81	92.98	97.32	Restriction	1.72	2.25	131.2	Normal	77	Abnormal
				40	No, 0 points	80	84.18	98.76	1	47.8	46.9	42.4	44.5																							
				40	Yes, 40 points	80	78.2	79.4	3	58.5	48.9	42.8	46.5	Improved	Improved	Improved	Present	No		Present	Negative		Normal	30	Yes, 40 points	70	80.29	77.12	77.09	Restriction	1.34	2.37	177	Normal	55.9	Abnormal
				5	No, 0 points	5	87.7	85	3	28.9	27.8	16.9	19.7	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	0	No, 0 points	0	82.02	82.25	85.03	Restriction	1.44	2.28	158.3	Normal	75.2	Abnormal
				0	No, 0 points	0	85.73	89.36	1	28.9	32.8	16.7	21.2																							
				50	Yes, 40 points	90	88.16	61.6	2	46.7	48.4	32.5	40.3	Improved	Improved	Improved	Present	No		Present	Negative		Normal	30	Yes, 40 points	70	78.26	59.79	59.2	Normal	1.34	1.39	103.5	Normal	72.1	Abnormal
				15	Yes, 40 points	55	81.3	59.2	2	36.9	38.4	26.5	30.9	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	Yes, 40 points	50	83.43	64.33	56.78	Obstruction	1.72	2.03	118.1	Normal	77.5	Abnormal
				20	Yes, 40 points	60	77.7	85.4	3	43.2	45.6	22.8	32.5	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	10	Yes, 40 points	50										
	MTB grown	Pan sensitive	Caseating granulomatous inflammation				90.17	93.84	3	32.5	35.6	20.2	29.8	Improved	Improved	Improved	Present	No		Absent	Negative		Normal				89.86	86.6	88.21	Obstruction	1.72	2.07	120.5	Normal	85.4	Normal
				30	Yes, 40 points	70	82.7	87.2	3	31.6	34.6	24.5	29.8	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	30	No, 0 points	30	88.17	86.83	88.17	Restriction	1.8	2.82	156.7	Normal	67.6	Abnormal
				20	Yes, 40 points	60	80.7	83.6	3	43.6	45.7	36.7	40.9	Improved	Improved	Improved	Present	No		Absent	Negative		Normal	20	No, 0 points	20	82.31	76.88	80.39	Restriction	1.71	2.51	146.5	Normal	96.4	Normal