



A Prospective Study on Functional Status and Quality Of Life Indices in Patients Treated With Pulmonary Tuberculosis in Tertiary Care Hospital in South India

Kavya N¹, Mohammed Hafeez^{1*}, Faseeh Kak Mohiddina¹, Haleemath Thabsheera¹, Balwant Singh¹, Thapashwi Bg¹, Vikram Loona¹, Midhila Gopinath¹, Emad Mir Abbas¹, L. Sreenivasa Murthy¹, BR Shivakumar¹, Shyamala K K², N Bhaktavatchalam¹

¹Department Of General Medicine, Dr. B. R. Ambedkar Medical College, Bengaluru.

²Department Of Pulmonology, Dr. B. R. Ambedkar Medical College, Bengaluru.

***Corresponding Author:**

Mohammed Hafeez

Assistant Professor, Department Of General Medicine, Dr. B. R. Ambedkar Medical College, Bengaluru

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Abstract

Background -Tuberculosis (TB) is an airborne disease caused by Mycobacterium tuberculosis that usually affects the lungs; but can affect other sites also. Despite the early identification of causative agent (1882) and development of effective chemotherapy, TB still continues to affect a huge proportion of the world population causing substantial disability. Though it is resulting in great economic disadvantage, little attention was given to the short- and long-term effects of PTB in terms of disability along with the effect this has on productivity and quality of life.

Objectives-To assess the pulmonary function and exercise tolerance among patients of pulmonary tuberculosis who completed therapy and To identify the factors associated with pulmonary function impairment. Also to assess quality of life in patients of pulmonary tuberculosis and assess factors affecting quality of life.

Method -It is a prospective comparative study with a sample size of 100, conducted in the department of Chest and TB Medicine, Dr B. R. Ambedkar Medical College, in the time period of November 2018 to May 2020. All the eligible patient attending Pulmonology OPD a and willing for study was included, after taking clearance from the institutional ethics committee. A detailed clinical history, physical examination, 6 minute walk test, St. George Respiratory Questionnaire(SGRQ), WHO disability assessment schedule II(WHODAS), WHO Quality Of Life Questionnaire(WHOQOL) and Spirometry was done.

Results-There was statistically significant decrease in total SGRQ score ($p < 0.001$). The change in WHODAS score was not statistically significant ($p = 0.39$). There was statistically significant improvement in physical health ($p = 0.006$), psychological health ($p = 0.01$) and environment domains ($p = 0.001$) of WHOQOL score.

Conclusion -Poor education, older age, smoking habit, lower BMI and radiological involvement were predictors of poor pulmonary function in this study. Quality of Life of cases improved over 6 months after completing treatment and pulmonary functions also improved. Simple measures like quality of life scores and 6-minute walk test can be used to identify patients at high risk of residual sequelae at places where pulmonary function testing is not available.

Keywords: pulmonary tuberculosis; anti-tubercular treatment; forced vital capacity; forced expiratory volume.

INTRODUCTION

Tuberculosis (TB) is an airborne disease caused by Mycobacterium tuberculosis that usually affects the lungs; but can affect other sites also.¹ TB caused ill-health for approximately 10 million people in 2016 globally and is one of the top ten causes of death worldwide. It is the leading cause of death from a single infectious agent.²

Tuberculosis incidence has increased to an extent that it was declared as a 'global emergency' by the World Health Organization in 1993.³ Though it is resulting in great economic disadvantage, little attention was given to the short- and long-term effects of PTB in terms of disability along with the effect this has on productivity and quality of life.^{4,5}

The long term well-being status of patients remains largely unknown after the successful short course chemotherapy regimens.⁶ India is a high burden country for TB as well as MDR TB and TB/HIV co-infection.⁷ Recent studies demonstrate suboptimal care for tuberculosis patients in India and adherence to standards in practice was generally lower than correct knowledge of those standards.⁸

Even if patient has completed his treatment, studies have documented respiratory symptoms persist in about 1/3rd of the patients who get declared cured and they present later to medical facilities.⁹ Despite microbiological 'cure', patients with PTB suffer significant long-term reductions in lung function and associated functional impairment and disability.¹⁰

The exact extent of the pulmonary impairment that could be attributable to PTB was not studied prospectively before. The aim is to study the functional disability and quality of life in pulmonary tuberculosis patients who completed antitubercular therapy, in a region with a high incidence of PTB and post tubercular residual sequelae.

Materials and methods

This study was an observational study of functional status and quality of life of patients with pulmonary tuberculosis within one month of completing antitubercular therapy and follows them up after six months for reassessment of their functional status and quality of life. After clearance from the institutional ethics committee this study was done on 100 Cases, who completed antitubercular therapy (selected from DOTS centre and outpatient department, Dept. of Pulmonology, in a tertiary care hospital in southern India). The study period was from November 2018 to May 2020.

All patients more than 18 years of age, diagnosed to have pulmonary tuberculosis by sputum microscopy or culture or gene Xpert; Broncho-alveolar lavage microscopy or culture or gene Xpert; trans bronchial lung biopsy suggestive of tuberculosis and completed antitubercular therapy from either DOTS or non-DOTS basis were included in this study. Patients with previous lung disease like asthma, COPD; or other coexisting medical conditions such as cardiac insufficiency, collagen diseases, silicosis or thoracic

surgery that could affect functional status and quality of life, were excluded from the study.

All the participants were explained about the study and informed consent was taken. Initial assessment regarding inclusion and exclusion criteria was done and details of the patient (age, gender, residence, occupation, educational status, smoking habits, and HIV seropositivity) were noted down in proforma. Chest X-ray findings were noted down and the severity of involvement was classified according to Wilcox grading (grade 1 for one zone involved without cavitation, grade 2 for two or three zones or one zone with cavitation and grade 3 for more than three zone involvement).²⁶ Then the patients were given WHODAS (World Health Organization Disability Assessment schedule), SGRQ (St. George Respiratory Questionnaire)²² and WHOQOL-BREF (World Health Organization Quality of Life Questionnaire)^{27,28} questionnaire in Hindi and Kannada. The responses were scored as per guidelines of the developers. All subjects underwent spirometry measurements at the end of the interviews according to the American Thoracic Society/ European Respiratory Society recommendations²⁹ for subject manoeuvre, techniques and quality control using Spirette respiratory tube based on ultrasound transit time measurement. Spirometer circuit leaks and equipment calibration were frequently checked to ensure performance. For each subject, the highest measurements of FVC and FEV1 from among at least three technically acceptable and reproducible manoeuvres were expressed at body temperature and pressure saturated with water vapor. Predicted values for FVC, FEV1, ratio of FEV1 and FVC (FEV1/FVC) were generated using prediction equations.³⁰ Lower limits of normal (LLN) for FEV1, FVC and FEV1/FVC were calculated using lower 95% confidence limits derived from the regression equation being used in our institute and were computed as the difference between the predicted value and 1.645 times the standard error of estimate or residual standard deviation of the regression equation.³¹ Severity of the pattern is described by FVC, if >70%, described as mild, 50-70% as moderate and <50% as severe abnormality.

The patients were assessed for 6-minute walk test which was done according to ATS guidelines for 6-minute walk test.²³ Patients were given rest for at least 10 minutes before the test. A 30 m hospital corridor, marked by coloured tape at each end was used. Subjects were instructed to walk from end to end at their self-selected pace, while attempting to cover as much distance as possible in the 6 minutes. The time and distance covered were recorded. In case any patient had chest pain, intolerable dyspnoea, or worsening vitals during the test, test was immediately stopped and the reason for stopping the test was noted. Pulse rate, oxygen saturation using pulse oximetry, respiratory rate and dyspnoea using the modified Borg scale³² were noted before and after the test and were entered in proforma along with distance covered.

Follow up

On follow up after six months, 64 of the patients came for the second visit. Remaining 36 patients could not be followed up due to Covid -19 pandemic. They were given questionnaires WHODAS in Hindi, SGRQ in Hindi and WHOQOL in Hindi which they answered as mentioned above. Spirometry and 6-minute walk test were repeated according to the protocol as described above.

Results

A total of 100 cases, who completed anti-tubercular therapy under RNTCP for pulmonary TB were included in the study. On follow up of the cases, 64 patients were able to come for the follow up visit. The mean age of cases was 36.8(SD-15.7) years. There were 57 males (55%) and 43 females (45%) among cases. The cases had urban residence in 81% (n=81). 10% (n=10) of the cases were illiterate. Most of the females were home makers(25%).

Smoking was seen in 23 cases, n=23(23%). Of the 100 cases, 6(6%) were HIV seropositive. Among the physical characteristics of the subjects, the mean height in cases was 1.59m (SD-0.09). 32% were underweight, 57% had normal and 11% were overweight. 40 % had normal Chest X ray findings of which 16% had Wilcox 1, 26% had Wilcox 2 and 18% had Wilcox 3 grade.

Factors associated with impairment of pulmonary function

Age, education, smoking habit, BMI and chest X-ray abnormality were the factors with statistical significance which were associated with abnormal lung function. Patients in the age group 25-50 had significantly higher percentage of abnormal lung function compared to other age groups (p=0.01). More patients in the higher educated group had normal pulmonary function as compared to the group with abnormal pulmonary function (p=0.001). Patients who had lower BMI (<18.5) had higher incidence of abnormal lung function (p=0.05). Most of the non-smokers (27 out of 38) had normal lung function and it was statistically significant (p=0.01). More the abnormality in chest X-ray higher was the percentage of abnormal lung function (p=0.01). There was no statistically significant difference with regard to sex, residence, comorbidity of HIV or sputum smear positivity.

6-minute walk test

The mean 6minute walk distance in cases group was 498.38m (SD-49.459). Those patients with abnormal pulmonary function tests were having lesser 6-minute walk distance as compared to those with normal pulmonary function tests (457.45m(SD-51.8) vs 504.73m(SD-54.4); p=<0.0001).

Increase in FEV1 caused increase in 6-minute walk distance (correlation coefficient = 0.017) as shown in scatter plot form in figure 1. Increase in FVC caused increase in 6-minute walk distance (correlation co-efficient = 0.58) described in pictorial form through a scatter plot figure 2.

There was no difference with regard to age, comorbidity of HIV, sputum smear positivity or residence. Mean 6-minute walk distance in smokers was low as compared to nonsmokers [470.17m (SD-60.223) vs 490.63m(SD-57.832)] but not statistically significant (p=0.21). Mean 6-minute walk test was lower in patients with abnormal chest X-ray (Wilcox grade III) than those with normal chest X-ray (p=0.02).

Quality of life

Quality of life as measured by WHODAS, SGRQ, WHOQOL scores varied among cases as shown in table 1. WHODAS scores were influenced by severity of chest X-ray, patients with normal chest X-ray had lesser disability compared to patients with abnormal chest X-ray (Wilcox grade II and III)

($p=0.01$). SGRQ score was also affected by severity of chest X-ray. Patients with abnormal chest X-ray (Wilcox grade III) had higher mean scores implying higher disability ($p=0.05$). Various factors affecting WHODAS and SGRQ score are summarized in table 1.

There was statistically significant difference with regard to social health domain (p value-0.03) with residence (social health was affected more in rural than urban patients) and insignificant difference in other domains with residence.

Correlation of QOL with pulmonary function

Those patients with normal spirometry had better quality of life scores and lesser disability scores. There was statistically significant correlation of QOL scores with percentage predicted values of FVC and FEV1. As the percentage predicted FEV1 increased, there was lower score of SGRQ implying lesser disability (correlation coefficient=-0.45) and is shown as a scatter plot in figure 3. As the percentage predicted FEV1 increased, WHODAS score decreased indicating lesser disability (correlation coefficient= -0.02) and is shown as a scatter plot in figure 4.

Comparison of the follow-up data of cases with baseline visit

On follow up 64 patients were able to come. Pulmonary function- there was improvement in mean %FVC and FEV1/FVC which was statistically significant as shown in the table 2. 6minute walk distance- there was statistically significant improvement in 6-minute walk distance on follow up visit (485.05, SD-58.74) as compared to baseline visit (470.95, SD-67.68) ($p<0.004$).

Quality of life indices

There was statistically significant decrease in total SGRQ score ($p<0.001$). The change in WHODAS score was not statistically significant ($p=0.39$). There was statistically significant improvement in physical health ($p=0.006$), psychological health ($p=0.01$) and environmental domains ($p=0.001$) of WHOQOL score. The comparison of various quality of life scores between baseline and follow up visit is summarized in table 3.

DISCUSSION

In this study we tried to quantify the amount of functional disability and its influence on exercise tolerance and quality of life. Previous studies have been mostly cross sectional in this regard, however we have tried to follow up patients at the end of completion of treatment and 6 months later, so that we can have a clue regarding duration of stabilization of lung damage after microbiological cure, on second follow up only 64 patients were able to attend. The baseline pulmonary function, exercise tolerance and quality of life were poor in cases which improved from the baseline on six months follow up. Poor pulmonary function was predicted by poor education, smoking habit, low BMI and radiological involvement; it couldn't be predicted by demographic profile, sputum smear positivity, HIV status or residence.

Prevalence and pattern of pulmonary impairment

The prevalence of pulmonary impairment in this study was 53%. Restrictive pattern (33% of the total cases) was more common than obstructive pattern (20% of the total cases). 85% of those patients with restrictive pattern and 75% of the patients with obstructive pattern of PFT had mild to moderate severity of pulmonary impairment. In previous studies the prevalence of pulmonary impairment after TB treatment varied from 18-96%.

Banu et al in a cross-sectional study done in India showed that 65% of patients ($n=363$) had pulmonary impairment 14 – 18 years after completing treatment with the commonest abnormality being restrictive defects occurring in 45% of the patients.³² The mean duration after completion of antitubercular treatment in this study was much longer (16.5 years) compared to our study (0 and 6 months).

A few studies had obstructive defects more common than restrictive defects. The most common functional alteration was obstructive lung disease (seen in 34.6%). A study done by Baig et al in a study in Rawalpindi evaluated patients of PTB sequelae with persisting symptoms and found obstructive pattern on spirometry in 55.3% ($n=47$).³⁴

A few studies evaluated patients of MDR-TB and found very high rates of pulmonary dysfunction. In

Our study, there were no MDR-TB patients. A study by Marcos et al revealed abnormal PFT pattern in 78% (n=18) of subjects with 24% obstructive and 18% restrictive patterns.³⁵ However, in this study all the included patients were MDR TB and received ATT multiple times in the past which might be the reason for higher prevalence of pulmonary dysfunction.

Predictors of pulmonary impairment

In this study the factors associated with impairment of lung function were higher age, poor education, smoking habit, lower BMI and radiological involvement. In previous studies, the factors associated with poor pulmonary function varied widely-factors like severity of radiological involvement, sputum smear positivity, smoking, HIV seropositivity, recurrent tuberculosis which couldn't predict impaired lung function in our study. A study done by Chuskin et al, revealed the risk factors for reduced pulmonary function as having had culture-positive pulmonary tuberculosis in the past, being over 50 years of age, having recurrent tuberculosis, and having a lower level of education.²⁴

In a cross sectional study done in Cameroon, Hugo et al found duration of symptoms [OR 1.08; 95% CI (1.01 – 1.15)] and fibrotic pattern [OR 3.54; 95% (1.40 – 8.95)] as independent risk factors for lung function impairment.³³

Duration of stabilization of lung function

In our study, we evaluated the patients at completion of treatment and 6 months later. There was improvement in lung function from the baseline visit indicating that the damage reaches nadir before completion of treatment (6 to 9 months after diagnosis). However further follow up is needed to assess when the pulmonary function near normalizes. Very few studies commented on the duration of stabilization of lung function. Hnizdo et al in a retrospective study in South Africa the loss of lung function was highest within six months of the diagnosis of tuberculosis and stabilized after 12 months when the loss was considered to be chronic.²

6-minute walk distance in pulmonary tuberculosis

In our study, there was poor exercise tolerance of patients at the end of completion of treatment which improved over the next 6 months. In a study done by Maguire et al, exercise tolerance (6MWW) rose by 12.3% (P < 0.001) at treatment completion as compared to at the time of initiation of treatment.²⁵

Quality of life after microbiological cure

In our study the QOL of cases was poor which improved over the next 6 months. The results in the previous studies were similar, though instruments used for assessment of quality of life varied widely between SF-36, WHOQOL-BREF and SGRQ.

Muniyadi et al showed in a study conducted in southern India that HRQoL (using SF-36 questionnaire) of TB patients one year after successful completion of treatment under the TB control programme was normal for most of the domains studied and was associated with age, literacy and employment, income, smoking, alcoholism and persistence of symptoms.³⁶ In a study done by Aggarwal et al in Chandigarh using WHOQOL-BREF scale Domain scores were generally better among men, urban residents, younger patients, patients with higher socio-economic status and those with less severe disease.³⁷

Limitations of the study

Our study excluded all patients with other chronic diseases in its design, so the population obtained was a subset of tuberculosis patients only and extrapolating it to entire cohort of tuberculosis patients is difficult. Our study included only 100 patients. A bigger study would have better power compared to the current study. There was a big amount of attrition owing to loss during follow up.

Conclusion

A significant number of pulmonary tuberculosis patients (53%) have residual sequelae even after completion of antitubercular treatment. Poor education, Higher age, Smoking and Radiological involvement was associated with higher odds of having poor pulmonary function (p=0.001). More involvement of lung parenchyma radiologically poorer the pulmonary function. However, larger studies are required to delineate the factors

predicting the pulmonary dysfunction so that those patients could be closely monitored even after treatment.

The quality of life and exercise tolerance are poor even after completion of treatment and those patients with poor quality of life have poor pulmonary function indicating that simple measures like quality of life scores and 6-minute walk test can be used to identify patients at high risk of residual sequelae at places where pulmonary function testing is not available.

The exact duration of stabilization of lung function couldn't be commented but the nadir of damage occurs within 6 months of initiation of treatment and it continues to improve till 6 months of completion of treatment. A study with longer and multiple follow up visits is needed to identify that.

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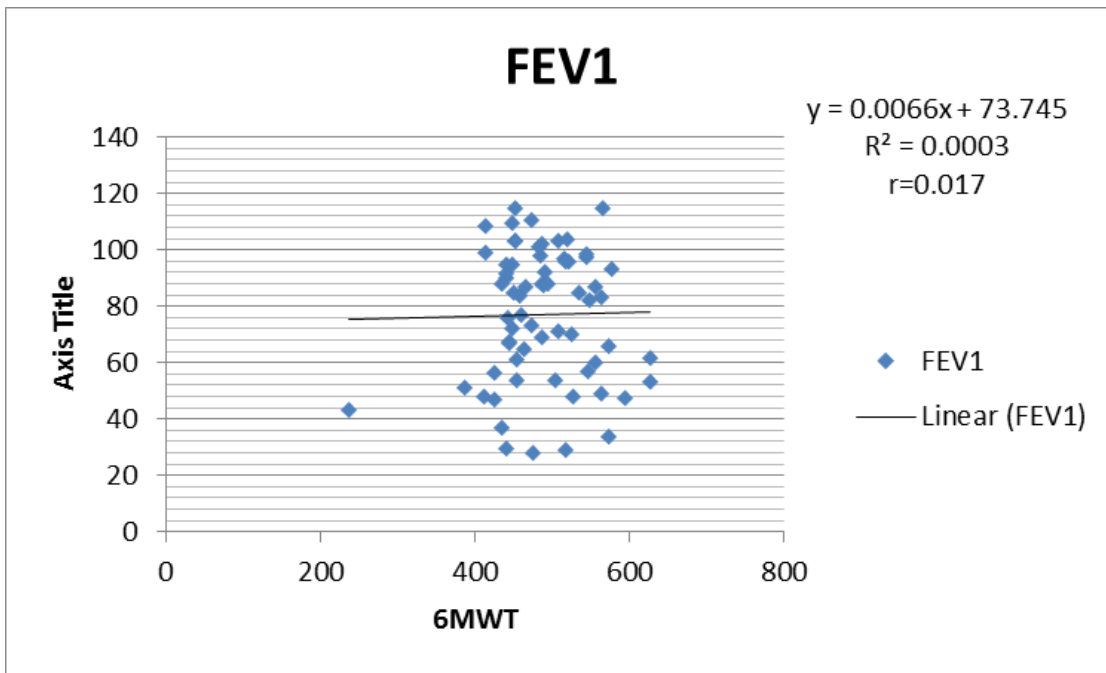


Figure 1: Relationship between 6mwt and FEV1.

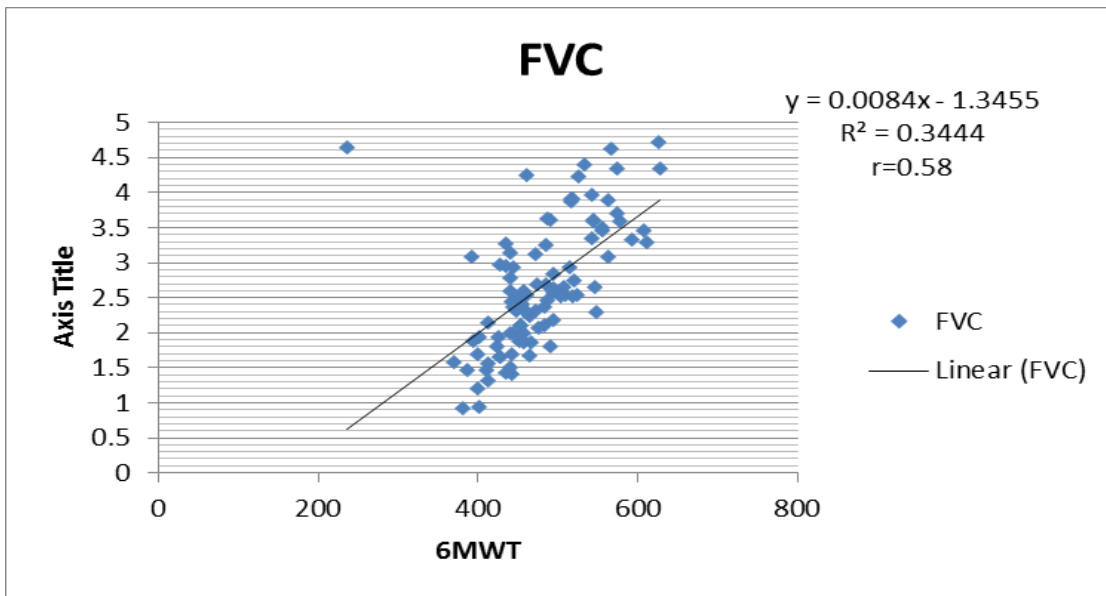


Figure 2: Relationship between 6mwt and FVC.

TABLES

Table 1: Various factors affecting SGRQ and WHODAS scores

Variable	SGRQ		WHODAS	
	Mean	SD	Mean	SD

<25	22.25	13.514	35.55	24.718
26-50	17.45	17.021	24.82	18.995
>50	19.63	11.237	25.00	13.949
p	0.15		0.53	
Non smokers	18.94	16.130	28.79	20.304
Smokers	19.78	13.589	26.22	22.302
p	0.84		0.65	
HIV Positive	11.40	7.369	15.00	1.732
HIV Negative	19.80	15.723	29.16	21.205
p	0.24		0.14	
Sputum positive	18.92	15.557	27.33	20.425
Sputum Negative	19.88	15.305	30.29	22.053

Table 2: Comparison of pulmonary function between baseline and follow up visit

	Mean ± SD	P value
FVC first visit	2.64±0.95	0.096
FVC 6 month visit	2.71±0.98	

%FVC first visit	76.39±21.43	0.0001
%FVC 6 month visit	78.74±20.83	
FEV1/FVC first visit	78.83±12.15	0.022
FEV1/FVC 6 month visit	77.55±13.10	
PEFR first visit	297.76±103.91	0.310
PEFR 6 month visit	362.00±519.30	
FEF25-75 first visit	133.86±76.76	0.152
FEF25-75 6 month visit	142.58±87.63	

Table 3: Comparison of 6-mwt and quality of life scores between baseline and follow up visit

Variables	First visit		Follow-up visit		P value
	Mean	SD	Mean	SD	
WHODAS score	30.81	24.314	26.13	16.972	0.39
SGRQ Score	23.30	16.638	19.17	15.381	0.001
6MWT	470.95	67.680	485.05	58.747	0.04
WHO –QOL BREF Score					
Physical domain	80.47	17.254	83.61	15.838	0.006
Psychological domain	79.02	18.635	82.21	15.670	0.011
Social domain	75.29	20.701	76.39	20.629	0.331
Environmental domain	75.92	17.520	80.50	16.926	0.001