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To study the effects of tuberculosis sequelae on functional capacity in male patients compared with age matched healthy individuals by using spirometry and six minute walk test

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ABSTRACT

Tuberculosis (TB) remains a major global health problem. It causes ill-health among millions of people each year and ranks as the second leading cause of death from an infectious disease worldwide after the human immunodeficiency virus. Aims & Objective: To study the effects of tuberculosis sequelae on functional capacity in male patients compared with age-matched healthy individuals by using spirometry and six-minute walk test. Total 40 male tuberculosis sequelae patients who were referred to physiotherapy outpatient setup from chest medicine department were screened for the study. 30 tuberculosis patients who met the inclusion criteria and accepted to participate were included in the study. 8 tuberculosis sequelae patients who did not satisfy the inclusion criteria were excluded from the study. 5 patients were HIV positive, 1 patient had lower limb deformity, 2 patients had undergone recent cardiac surgery. 2 patients refused to participate in the study. 50 subjects diagnosed with osteoarthritis knee were included in the study. The data was collected by questionnaire form and was analyzed using SPSS 14.0 and graph pad 6.7 version. Correlation of was done using Pearson correlation coefficient. Result: The Mean difference of six-minute walk distance between Group A and Group B was 150.30. It was found to be statistically significant at $P < 0.0001$ (95% confidence interval) as measured by applying students unpaired t-test. From the present study, it is concluded that the result indicates that individuals with knee osteoarthritis report, episodes of knee instability during activities of daily living. Instability affects physical function which can be explained by contributions from other impairments such as knee pain, range of motion and quadriceps strength. There was a statistically significant increase in respiratory rate in both the groups with $P < 0.0001$ for group A as measured by applying Wilcoxon matched-pairs signed-ranks test & $P < 0.0001$ for group B as measured by applying paired t-test. The mean change in respiratory rate was statistically significant between Group A & Group B with $P < 0.0001$ as measured by Mann-Whitney Test. The present study was attempted to analyses the effects of tuberculosis sequelae on functional capacity in male patients compared with age-matched healthy individuals by using spirometry and six-minute walk test. There was a significant difference in physical functional capacity between a group of normal middle-aged people and those with tuberculosis sequelae. In the TB sequelae group, there was a considerable impact of TB sequelae on cardio-respiratory endurance which affects the daily activities.

Keywords— FVC and FEV1, Spirometry, Mercury sphygmomanometer, Stethoscope

1. INTRODUCTION

Tuberculosis (TB) remains a major global health problem. It causes ill-health among millions of people each year and ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (HIV).¹ Jie Wu et al. (2012) reported that tuberculosis mainly affects the people in developing countries with low socio-economic status.² The latest estimates included in WHO report were that almost 9 million new cases in 2011 and 1.4 million TB deaths (990 000 among HIV negative people and 430 000 HIV-associated TB deaths) around the world¹. India ranked first among the countries having largest number of incidents (2.0 million–2.5 million) of TB cases in 2011. It is estimated that it forms about 26% of worldwide TB cases, despite the availability of treatment for TB that ensures curing of most of the cases. Short-course regimens of first-line drugs that can cure around 90% of cases have been available since the 1980s¹. Tuberculosis is a bacterial disease that spreads from one person to another principally by airborne transmission. It is caused by multiplication of bacilli belonging to the genus Mycobacterium. The principal bacterium responsible for the disease is Mycobacterium tuberculosis (the Koch bacillus).³ The histopathological findings resulting from tuberculosis include the formation of caseous granuloma, tissue liquefaction and formation of pulmonary cavities.⁴

Tuberculosis of the lungs often results in diffuse fibrotic changes to lung tissue as well as lung tissue consolidation leading to a reduction in overall lung compliance. Consequently, the functional status of a person following tuberculosis is diminished secondary to poor ventilation and gas exchange leading to progressive dyspnea, deconditioning, and thus, an overall decline in functional status.⁴The presence of extensive residual lung lesions may be a predictor of permanent disability following tissue destruction, cor pulmonale and susceptibility to opportunistic infections, leading to reduced quality of life.⁴ **Males are also known habitual smokers.** C. B. Holmes et al. (1998) reported that prevalence and mortality rate of TB is higher in adolescent and older male patient than females.⁵ A study done by J Y Wang et al. (2007) reported that smoking is significantly associated with radiographic manifestations of pulmonary tuberculosis, but not with death among PTB patients.⁶ C Kolappan et al. (2002) conducted a study on tobacco smoking and pulmonary tuberculosis and reported that there is a positive association between tobacco smoking and pulmonary tuberculosis.⁷

Jurgen Rehm et al. (2009) conducted a systemic review on the association between alcohol use, alcohol use disorders and tuberculosis. They reported that heavy alcohol use constitutes a risk factor for incidence and re-infection of TB.⁸

2. AIMS AND OBJECTIVES

- To study the effects of tuberculosis sequelae on functional capacity in male patients compared with age matched healthy individuals by using spirometry and six minute walk test.
- To assess the functional capacity in male patients with pulmonary tuberculosis sequelae and compare it with age matched healthy individuals on:
 - a) FVC (% predicted) and
 - b) FEV1 (% predicted)
- To assess the functional capacity in male patients with pulmonary tuberculosis sequelae and compare it with age matched healthy individuals in six minute walk test on:a) Heart rate,b) Systolic blood pressure,c) Diastolic blood pressure,d) Respiratory rate,e) Distance covered at the end of six minute walk test.

3. MATERIAL AND METHODS

Permission and approval to carry out the research work was obtained from the head of institution and institutional ethical committee.

Study design: Observational case control study.

Place of study: The study was conducted at outpatient Physiotherapy set up.

Population of the study:

Experimental group: Male patients with pulmonary tuberculosis sequelae referred to outpatient physiotherapy department.

Control group: Normal, healthy male individuals.

Duration of study: The study was conducted in physiotherapy department clinical set up from September 2012 to October 2013.

Selection Criteria

Inclusion criteria:

Experimental group:

Male Patients with pulmonary tuberculosis sequelae between the age group of 40-60 years who fulfilled the guidelines of American Thoracic Society for spirometry and six minute walk test and found to be sputum negative after completing at least 6 months of drugs treatment for TB.

Control group:

Healthy male subjects in the age group of 40-60 years.

Exclusion criteria:

In both the groups, the subjects were excluded if they met with the following exclusion criteria.

1. History of any degenerative neuromuscular disease, coronary artery disease, myocardial infarction and any cardiac or pulmonary surgeries.
2. History of spine and lower limb fracture or deformities.
3. Severe hemodynamic instability.
4. H.I.V +ve.
6. Current smokers.
7. Current alcoholic.
8. People engaged in exercises for fitness.

Sample size:

Experimental Group: Total 40 male tuberculosis sequelae patients who were referred to physiotherapy outpatient setup from chest medicine department were screened for the study. 30 tuberculosis patients who met the inclusion criteria and accepted to participate were included in the study. 8 tuberculosis sequelae patients who did not satisfy the inclusion criteria were excluded from the study. 5 patients were HIV positive, 1 patient had lower limb deformity, 2 patients had undergone recent cardiac surgery. 2 patients refused to participate in the study.

Control Group: Total 30 normal male healthy individuals who were accompanying patients coming to the chest OPD and met with inclusion criteria formed the population for control group in order minimize variance. In order to minimize the variance in population, we included normal male healthy individuals coming to chest OPD along with patients. The chest OPD had a variance population from the rural as well as urban and from the surrounding states as well. Thus we tried to minimize population variance.

Materials used for study: Spirometer Med Graphics^R BREEZESUITETM, Mercury sphygmomanometer, Stethoscope, Worksheets on a clipboard, Cone/marker, Measuring tape, Stop watch, Arm chair, Mechanical lap counter, Stadiometer.

Outcome measures:-Patients were assessed for the following outcome measures.

- 1) FVC (% predicted).
- 2) FEV1 (% predicted)

Six Minute Walk Test: Heart rate (b.p.m), Systolic blood pressure (mmhg), Diastolic blood pressure (mmHg), Respiratory rate (c.p.m), Distance covered at the end of six minute walk test (m).

4. PROCEDURES FOR DATA COLLECTION

The purpose and methodology of the study was explained to all the patients in detail and they were also informed about the risks, in a language that they understood. They were made aware about the right to terminate the participation at any time during the procedure. All patients acknowledged their understanding of the study and their willingness to participate by providing a signed consent form. Patients were evaluated according to the proforma. The demographic details like age, gender, occupation, contact number and address was collected. Brief history of origin and duration of tuberculosis and any associated problems were recorded.

4.1 Procedure

Spirometry: Patients were explained about the spirometer Graphics^R BREEZESUITETM 6.2 and how to use, in a language they understood.

The spirometer – machine used to record spirometry – was calibrated every morning to ensure that it recorded accurate values before it was used. The temperature and barometric pressure was entered into the spirometer every morning, as variation in these measures does affect the final results.^{16,17} Each patient was clinically stable and made to sit in a firm armchair straight with head erect, nose clip in place, and holding the mouthpiece tightly between the lips. Initially, he was made to breathe in and out at the normal quiet breathing to record the tidal flow–volume loop. When the patient was ready, the physiotherapist instructed him to inhale maximally to TLC and then exhale as fast and as completely as possible and the FVC and FEV1 were recorded. This test was then repeated three times to ensure reproducibility in order to meet quality control criteria (American Thoracic Society or ATS criteria) the best of three results was selected.^{16,17}

Six Minute Walk Test: A rest period of 15 minutes was given to the patient before performing the six minute walk test. Patients were explained about the 6-minute walk test (6MWT) in a language that they understood. Patient's usual medical regimens were continued. They were advised to take light meal before early morning and should not have exercised vigorously within 2 hours of beginning the test. Each patient performed 6- minute walk test in well equipped cardio- respiratory physiotherapy lab with an attached indoor hallway, along a long, flat, straight, enclosed corridor with a hard surface. The walking course was 30 m in length. The length of the corridor was marked every 3 m. The turnaround end points were marked with a cone. A starting line, which marked the beginning and end of each 60-m lap, was marked on the floor using brightly coloured tape. Patients' preparation were done by asking them to wear comfortable clothing, appropriate shoes or footwear for walking.¹² Then each patient was made to sit at rest in a chair, located near the starting position, for at least 10 minutes before the test started. During this time physiotherapist measured all required basal parameters i.e. heart rate, blood pressure and respiratory rate.¹² The resting arterial BP was obtained using a sphygmomanometer. Cuff width, position, tightness, and deflation rate were controlled in accordance with American Heart Association standards.¹⁸ Resting HR was determined using a digital stopwatch by counting the left radial arterial pulse for 30 seconds and multiplying the value by 2.

Respiratory rate was measured with the patient sitting in chair by directly observing the thoracic movements during respiration. The number of cycles taken completely for 30 seconds was observed and it was multiplied by 2 to get the respiratory rate. Then patient was made to walk as far as possible for six minutes in the hallway with their self-selected pace for a period of six minutes. The patient was instructed to report any discomfort, chest pain, intolerable dyspnea, leg cramps, staggering, diaphoresis, pale or ashen appearance and allowed to stop if any of this symptoms produced. Immediately after completion of the test for six minutes, the post test parameters i.e. heart rate, blood pressure, respiratory rate and total distance walked by the patient was recorded. Total distance covered at the end of the 6 minutes was calculated by multiplying number of laps x 60 meters + final partial lap distance. The patients were monitored till all the parameters recovered to normal.

The data was subjected to statistical analysis.

5. DATA ANALYSIS

- Following dependent variables were used for statistical analysis:
- FVC (% predicted), FEV1 (% predicted), Heart rate (HR), Blood pressure (BP) and Respiratory Rate (RR), six minute walk distance (6MWD).
- The data was analyzed statistically by using GraphPad InStat-3 softwares.
- Various statistical measures such as mean, standard deviation (SD), range, tests of significance and 95% Confidence interval were used for this purpose.
- The data was tested for normality using the Kolmogorov-Smirnov Z test with $p < 0.05$. If the sample data passed the normality test, the parametric test i.e. paired t-test for mean pre and post comparison within group and unpaired t- test was used to compare mean and mean changes between groups. If the sample data failed the normality test, nonparametric test i.e. Wilcoxon matched-pairs signed-ranks test and Mann-Whitney Test of significance were used with $p < 0.05$.
- The level of significance was set at $p < 0.05$.

Table 1: Distribution of patients according to age-group.

Age-group	No. of patients	Percentage
40-44	7	23.33%
45-49	6	20%
50-54	8	26.66%
55-60	9	30%
Total	30	
Mean± SD	50.63 ± 5.92	

Table 2: Showing comparison of mean FEV1 % predicted between Group A and Group B.

	Group A	Group B
Mean	44.033	92.500
Std. Deviation	± 9.152	± 9.235
Mean diff.	48.467	
p value	< 0.0001***	

Interpretation: The table 4 and graph 4 shows the comparison of mean FEV1 (% predicted) of Group A and mean FEV1 (% predicted) of group B. The Mean difference of FEV1 (% predicted) between Group A and Group B was 48.467. It was found to be statistically significant at P<0.0001(95% confidence interval) as measured by applying students unpaired t test

Table 2: Showing comparison of mean pre-test & post-test Heart Rate in six minute walk test for Group A & Group B

	Group A		Group B	
	Pre	Post	Pre	Post
Mean (Std. Deviation)	83.333 (±10.230)	121.73 (± 20.313)	74.167 (±5.395)	80.433 (± 5.008)
Median (Range)	83 (66 - 102)	128 (86 - 154)	75 (66 -82)	82 (70 - 88)
P Value	< 0.0001***		< 0.0001***	
Mean Change(Std Deviation)	38.400 (± 17.328)		6.267 (± 2.288)	
P Value	< 0.0001			

There was statistically significant increase in heart rate in both the groups with P< 0.0001for group A as measured by applying Wilcoxon matched-pairs signed-ranks test & P< 0.0001 for group B as measured by applying paired t test. The mean change in heart rate was statistically significant between Group A & Group B with P< 0.0001 as measured by Mann-Whitney Test. The present study was designed to study the effects of tuberculosis sequelae on functional capacity in male patients compared with age matched healthy individuals by using spirometry and six minute walk test. Pulmonary impairment after tuberculosis is associated with disability worldwide and requires more aggressive case prevention strategies and post treatment evaluation. Middle age males are the main earning members of family who are more prone to tuberculosis due to predisposing factors like smoking, alcohol and poverty etc. Post-tuberculosis patients may have limited exercise tolerance and significant disability which may affect daily activities thus the study was conducted on 30 male tuberculosis sequelae patients (group A) and compared with 30 male healthy individuals (group B). The patient’s age ranged between 40-60 years with a mean age of 50.77 ± 5.971. The healthy individual’s age ranged between 40-60 years with a mean age of 50.633 ± 6.239. Demographic details of the subjects between both the groups were matching at baseline hence both the group were comparable. The result of the present study showed that there was a significant reduction in FVC and FEV1 in group A as compared to group B. (p < 0.0001).

The findings of this study are consistent with the study done by Jotam G. Pasipanodya et. al.(2007) on pulmonary impairment after tuberculosis and found that FVC, FEV₁, FEV₁/FVC ratio, and the mid expiratory phase of forced expiratory flow were significantly lower in the treated pulmonary tuberculosis patients than in the comparison group. Mikhail Chushkin et al. (2011) conducted a study on the impairment of respiratory function in patients with treated pulmonary tuberculosis and found that FVC, FEV₁, FEV₁/ FVC ratio significantly reduced in treated pulmonary tuberculosis patients. Di Naso F C et al (2011) conducted a study on pulmonary tuberculosis sequelae patients who completed treatment within a period of 6 months (group I) and multidrug-resistant pulmonary tuberculosis patients who completed treatments of longer duration after the failure of the initial treatment (group II) and suggested that patients with pulmonary tuberculosis had severe respiratory and functional impairments. Patients with multidrug resistance pulmonary tuberculosis who had undergone multiple treatment had more severe respiratory and functional impairments than patients who had just a single treatment. Rita Santa Cruz et al (2008) conducted a study on pulmonary tuberculosis: association between extent of residual lung injury and pulmonary function changes and suggested that large number of residual radiographic lesions and breathing dysfunction in pulmonary tuberculosis sequelae corresponded to alteration of lung functions. Eva Hnizdo (2000) preformed a study on chronic pulmonary function impairment caused by initial and recurrent pulmonary tuberculosis following treatment and suggested that tuberculosis can cause chronic impairment of lung function which increases incrementally with the number of episodes of tuberculosis. The results of our studies are consistent with the studies done by Singla N. et al (2009), Maguire G P et al (2009), S. de Vallière et al (2004), with significant reduction in FVC and FEV1 showing lung function impairment after tuberculosis sequelae.

6. CONCLUSION

The present study was attempted to analyse the effects of tuberculosis sequelae on functional capacity in male patients compared with age matched healthy individuals by using spirometry and six minute walk test. There was a significant difference in physical functional capacity between a group of normal middle aged people and those with tuberculosis sequelae. In the TB sequelae group, there was a considerable impact of TB sequelae on cardio-respiratory endurance which affects the daily activities.

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