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Original Article

Efficacy of early structured pulmonary rehabilitation program in pulmonary function, exercise capacity, and health-related quality of life for patients with post-tubercular sequelae: A pilot study

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ABSTRACT

Background: Residual structural changes in the lung along with pulmonary impairment remain in a large number of patients of tuberculosis after microbiological cure. The aim of this study was to determine whether 12 weeks of a structured pulmonary rehabilitation program (PRP) administered along with antitubercular treatment improved the baseline measurement of pulmonary function, exercise capacity, and health-related quality of life (HRQOL).

Methods: A pilot study with single blind randomized control design was carried out in a tertiary care chest center. Spirometry, exercise capacity by 6-minute walk distance (6MWD), and HRQOL using St George respiratory questionnaire (SGRQ) score were evaluated in 62 patients, divided into 2 groups: intervention group (IG) ($n = 31$) and control group (CG) ($n = 31$) patients at baseline and at end of 12 weeks. IG completed 12 weeks of PRP.

Results: Significant difference in forced expiratory volume in 1st second (FEV1) (2.94 L at baseline vs 3.18 L at end of 12 weeks of PRP, diff 0.239 L, p-0.001), forced vital capacity (FVC) (3.43 L vs 3.75L, p -0.00), 6MWD (440.6 m vs 574.6 m, $p = 0.00$), and SGRQ score of at baseline (24.5 m vs 11.1m, $p = 0.00$) was seen in the IG. At end of 12 weeks, there was statistically significant difference in FEV1(L) ($p = 0.01$, 95% CI -0.317 to -0.046), FVC(L) ($p = 0.00$, 95% CI -0.359 to -0.139),6MWD(m) ($p = 0.00$; 95% CI -101.6 to -49.57) between CG and IG. There was no statistically significant difference in SGRQ scores between the 2 groups ($p = 0.231$).

Conclusion: PRP administered along with treatment is beneficial in reducing residual pulmonary impairment.

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Introduction

Tuberculosis (TB) continues to be a major global health problem despite the efforts of the World Health Organization (WHO) and governments of all countries to unite and end TB by 2035. It is one of the top 10 causes of death worldwide from a single infectious agent ranking above HIV.[1] India accounts for one-fourth of the global TB burden. An estimated 28 lakh cases occurred in India out of the global incidence of 104 lakhs, accounting for one-fourth of the world's TB cases, and 4.23 lakh people died due to TB in 2016.Eighty-four percent of all TB cases are pulmonary.[2] The National Strategic Plan (NSP) crafted in line with the global efforts like WHO end TB strategy aims to eliminate TB from India by 2025. To achieve this goal, NSP has set the target of 80% reduction in TB incidence, 90% reduction in TB mortality, and 0% patients having catastrophic expenditure due to TB. The NSP recommends focusing on detection of all cases, treatment, prevention, and building of the existing policies.[3] There is no emphasis on following up of patients after successful treatment completion. In some patients of pulmonary tuberculosis, microbiological cure or successful treatment completion is not the end of a disease but the beginning of a new one in terms of residual symptomatic, anatomical, and functional impairment.

Several studies have shown that despite adequate treatment pulmonary tuberculosis (PTB) may lead to chronic bronchial and parenchymal structural changes such as bronchiectasis, emphysema, and pulmonary functional impairment. Pulmonary impairment after tuberculosis (PIAT) may be obstructive, restrictive, or mixed pattern, ranging from normal to severe impairment contributing to increased morbidity.[4,5,6] In the context of the Armed forces, the functional impairment following treatment of pulmonary tuberculosis in serving soldiers leads them to be made permanently unfit for duty or being unfit for active combat duties causing loss of trained man power. The role of early pulmonary rehabilitation (PR) incorporated along with chemotherapy in preventing or decreasing the PIAT has not been studied in the armed forces. PR has been recognized as a core component in the management of chronic respiratory diseases such as chronic obstructive pulmonary diseases (COPD), bronchiectasis, interstitial diseases, cystic fibrosis, asthma with improvement in symptoms, exercise tolerance, and quality of life. There have been few studies showing benefits of PR in cases of pulmonary impairment after tuberculosis.[7,8] Literature search showed no published data for a pulmonary rehabilitation program (PRP) of 12 weeks in Armed forces. This study was planned and conducted to determine whether a structured PRP of 12 weeks duration incorporated along with continuation phase of chemotherapy would help in improvement of pulmonary function, exercise capacity, and quality of life in patients of PTB before treatment completion.

Material and methods

This pilot study was carried out in a tertiary care center of the armed forces between October 2015 to October 2017. The patients in the study were drawn from the patients admitted for institutional treatment of pulmonary tuberculosis. All new cases of pulmonary tuberculosis >18 years of age (New cases defined as per Revised National Tuberculosis Control Program guidelines),[2] having completed the intensive phase or 2 months of treatment and became sputum smear negative, were symptomatic with breathlessness on exertion as per Modified Medical Research Council Scale (MMRC), and had pulmonary function impairment on spirometry as per Armed Forces guidelines were included in the study. Airway obstruction was defined as an forced expiratory volume in 1st second (FEV1)/forced vital capacity (FVC) ratio of <70% and an FVC of >80% predicted, restrictive defects as an FEV1/FVC ratio of >70% with an FVC of <80% predicted, and combined defects were FVC of <80% predicted and an FEV1/FVC ratio of <70%.

All cases of pulmonary tuberculosis who remained sputum smear positive at the end of 2 months of treatment, all patients with comorbidities which cause immunosuppression such as diabetes mellitus and HIV infection, and all patients with preexisting lung diseases like bronchial asthma and COPD were excluded. All participants gave consent for participation in the study. The ethical clearance was obtained from the institutional ethics board committee.

Sample size was calculated with samplesize.net, using the 2-group analytical study comparing mean of a continuous measurement in 2 samples. It was estimated from a previous study[9] which showed a difference of 54 m in the 06 min walk distance between the intervention and control group (CG), assuming that the CG would walk 54 m less than the intervention group (IG) with a standard deviation of 74 m. A sample size of 31 was required in each group to establish a significant difference at a p level of 0.05 and power of 80%. Sixty-two patients were recruited consecutively into the study. The selected participants were randomly allocated into 2 groups: IG and CG by an independent research assistant by a single blinded randomized control study design. The principal investigator (PI) was blinded to the group allocation. The principal researcher then administered a detailed proforma for obtaining the demographic and clinical data of all the participants. Spirometry was performed by a trained technician using the Jaeger whole body box plethysmograph. It was carried out according to the techniques mentioned in the Spirometry manual (chest research foundation) with special reference to American Thoracic society of Standardization of Spirometry. The 6 min walk test was performed by a trained technician as per new American Thoracic Society (ATS)/European respiratory Society (ERS) technical guidelines.[10] St George respiratory questionnaire (SGRQ) was administered to each participant under supervision by the PI to ascertain the health-related quality of life (HRQOL). SGRQ questionnaire has designed to measure health impairment in asthma, COPD, and bronchiectasis. It has also been validated for use in pulmonary impairment after treatment of pulmonary tuberculosis with a mean difference of 13.5 units showing a significant impact on quality of life in these patients.[11] Only those participants selected in the IG were started on the 12 weeks of supervised PRP as described below. The PRP was implemented under the supervision of a trained and qualified respiratory physiotherapist and a respiratory physician. The PR protocol was based on the ATS guidelines on PR 2013.[12] Participants in CG were encouraged to do their own exercises and running without any supervision which is the usual protocol followed in this center. The PI who was blinded to group allocation administered and entered the values of all parameters at baseline and end of 12 weeks for all the participants.

Based on the ATS guidelines, a 12-week structured PRP was designed. All 31 patients in the IG completed 12 weeks of PRP. It consisted of exercise training, breath retraining, and education. Exercise was done for 1 h per day under supervision of respiratory physiotherapist for 5 days a week. Exercise training consisted of endurance training with high-intensity exercises gradually increasing in duration and intensity over 12 weeks. It included brisk walking and stationary cycling. High-intensity exercises were interspersed regularly with periods of lower intensity exercises. Strength training with weights was given for both upper and lower limbs. Inspiratory muscle training was done using a Philips Respironics, threshold inspiratory muscle trainer (IMT). This device incorporates a flow-independent one-way valve to ensure consistent resistance and features an adjustable specific pressure setting (in cm H20), which was set by the physiotherapist and increased incrementally during the PRP. When patients inhale through threshold IMT, a spring-loaded valve provides a resistance that exercises respiratory muscles through conditioning. The participants received a high-intensity IMT. The training load was adjusted to 30% of each patients maximum inspiratory pressure using a previous study.[13] Total training time was 21 min and 6 cycles of 30 breaths (2 cycles, 3 times daily). The participants of IG trained for 7 days a week for 12 weeks using the threshold IMT with gradually increasing load. Each cycle consisted of 3.5 min of resistive breathing followed by 1 min of rest. Patients also attended education sessions on breath training, stress management, and lung health.

Demographic data and baseline data for lung function, FEV1, FVC, FEV1/FVC, 6-minute walk distance (6MWD), and SGRQ score were entered in a predesigned clinical proforma for both the intervention and CGs by the PI at baseline and end of 12 weeks. The outcome variable in this study is the change in lung function parameters, FEV1, FVC and FEV1/FVC, 6MWD, and SGRQ score between baseline and end of 12 weeks for each group and also compared between the 2 groups.

Data analysis was performed by using SPSS (Statistical Package for Social Sciences), version 23.0. Paired *t* test was used to evaluate the change in pulmonary function parameters (FEV1, FVC, FEV1/FVC), 6MWD, and SGRQ score between baseline and end of 12 weeks within each group. Student *t* test was used to compare the variables between the 2 groups. P-value < 0.05 was considered as significant.

Results

Sixty-two patients who fulfilled the inclusion criteria were included in the study. There were 31 patients in each group, IG and CG, respectively. All the patients in the IG completed 12 weeks of PRP. All the patients in the CG also completed their own unsupervised exercise of 12 weeks. Table 1 shows the demographic profile of all the participants. All participants were male as this study was done in a military hospital where all serving soldiers with pulmonary tuberculosis are admitted for institutional treatment for at least 20 weeks. 37/62 (60%) participants had restriction, 14/62 (22.5%) had obstruction, and 11/62 (17.5%) had mixed pulmonary impairment on spirometry. The anthropometric parameters, 6MWD and HRQOL (SGRQ) scores were comparable between the 2 groups with no statistical difference in baseline values of spirometry, 6MWD, and SGRQ scores (Table 2).

Intragroup analysis was done for each group. In the CG, the difference in values for FEV1 at baseline and at end of 12 weeks showed an increase in mean FEV1, which was statistically significant. There was no statistically significant difference in other parameters of pulmonary function FVC and FEV1/FVC.

In the IG, the values for difference between the baseline and at end of 12 weeks for FEV1 and FVC were statistically significant. The difference in the 6MWD and SGRQ scores between the baseline and end of 12 weeks was statistically significant in both groups (Table 3). Comparing the 2 groups for difference in parameters at baseline and end of 12 weeks (t test for equality of means), difference of FEV1, FVC, and 6MWD and MMRC score was statistically significant. The difference between the SGRQ scores at end of 12 weeks between CG and IG was not statistically significant ($p = 0.231$) (Table 4).

Table 1 – Demographic profile of the participants at baseline.

Characteristic	CG (n = 31), Group 1	IG (n = 31), Group 2
Age*	26 (5)	25 (5)
Gender	M-31	M-31
Current smoker	2 (6%)	1 (3%)
Ex-Smoker	14 (45%)	13 (42%)
Never Smoked	15 (49%)	17 (55%)
Height (cm)*	173 (4.08)	172 (5)
Weight (kg)*	65 (9.5)	65 (10)
BMI (kg/m^2)*	22 (2.8)	21.9 (2.75)
FEV1(L)*	2.857 (0.516)	2.942 (0.678)
%FEV1	68.81 (8.132)	71.92 (14.84)
FVC(L)*	3.521 (0.933)	3.434 (0.743)
%FVC	72.11 (8.415)	71.183 (13.93)
FEV1/FVC(%)*	80.02 (6.10)	84.327 (9.68)
6MWD(m)*	462.032 (69.83)	440.645 (70.862)
MMRC Score*	1.6 (0.3)	1.58 (0.29)
SGRQ Score*	24.69 (10.71)	24.527 (11.81)

* All values are given as mean and standard deviation.
CG, control group; IG, intervention group; 6MWD, 6-minute walk distance; SGRQ, St George respiratory questionnaire; MMRC, Modified Medical Research Council scale; FEV1, forced expiratory volume in 1st second; FVC, forced vital capacity; BMI, body mass index.

Table 2 – Difference in baseline characteristics of the 2 groups.

Characteristic	Group 1 CG	Group 2 IG	Mean difference	p value
Age (yrs)	26 (5)	25 (5)	−1	0.4341
Height (cm)	173 (4.08)	172 (5)	−1	0.3917
Weight (kg)	65 (9.5)	65 (10)	0.00	1.00
BMI (kg/m^2)	22 (2.8)	21.9 (2.75)	−0.010	0.8877
MMRC score	1.6 (0.3)	1.58 (0.29)	−0.02	0.7905
FEV1(L)	2.857 (0.516)	2.942 (0.678)	0.085	0.5806
FVC(L)	3.521 (0.933)	3.434 (0.743)	0.087	0.6861
FEV1/FVC	80.02 (6.10)	84.327 (9.68)	4.3	0.04
6MWD(m)	462.032 (69.83)	440.645 (70.862)	−21.38	0.236
SGRQ score	24.69 (10.71)	24.527 (11.81)	0.163	0.954

CG, control group; IG, intervention group; 6MWD, 6-minute walk distance; SGRQ, St George respiratory questionnaire; MMRC, Modified Medical Research Council scale; FEV1, forced expiratory volume in 1st second; FVC, forced vital capacity; BMI, body mass index.

Table 3 – Difference in parameters between baseline and end of 12 weeks in both groups.

Parameters	CG				IG			
	Mean value at baseline	Mean value at 12 wks	Mean change	p value	Mean value at baseline	Mean value at 12 wks	Mean change	p value
FEV1(L)	2.857	2.898	0.041	0.00	2.942	3.182	0.239	0.001
FVC(L)	3.521	3.680	0.159	0.097	3.434	3.745	0.310	0.00
FEV1/FVC	80.02	80.07	1.98	0.038	84.327	85.22	0.890	0.506
6MWD(m)	462.03	520.48	58.45	0.00	440.6	574.6	134	0.00
SGRQ	24.69	11.68	13.01	0.00	24.53	11.61	12.9	0.00

CG, control group; IG, intervention group; 6MWD, 6-minute walk distance; SGRQ, St George respiratory questionnaire; FEV1, forced expiratory volume in 1st second; FVC, forced vital capacity.

Table 4 – Comparison of the change in parameters between baseline and end of 12 weeks between IG and CG.

Parameters	Mean difference	Std. error difference	p value	95% CI
FEV1(L)	0.18129	0.06781	0.01	-0.3169 to 0.0456
FVC (L)	0.24870	0.05475	0.00	-0.3585 to 0.1388
6MWD	75.58065	13.00284	0.00	−101.59 to 49.57
SGRQ score	4.62072	3.79835	0.23	−12.31 to 3.07

CG, control group; IG, intervention group; 6MWD, 6-minute walk distance; SGRQ, St George respiratory questionnaire; FEV1, forced expiratory volume in 1st second; FVC, forced vital capacity; CI, confidence interval.

Discussion

Unlike other infectious diseases, pulmonary tuberculosis has been associated with significant, prolonged impairment of pulmonary function, exercise tolerance, and quality of life after microbiological cure.[14] Various studies have shown pulmonary function impairment of different patterns (obstructive, restrictive, or mixed) and severity in treated cases of pulmonary tuberculosis.[4,15–17] In the current national and international guidelines for treatment of tuberculosis, there is no emphasis on regular follow-up of treated cases of tuberculosis. Thus, PIAT remains an underrecognized cause of prolonged disability. The PR has been recognized as an effective non-pharmacologic intervention in chronic respiratory diseases specially COPD, bronchiectasis, cystic fibrosis, etc. The PIAT has not yet been included in the indications for PR. There are a few studies showing the benefits of PR in chronic lung impairment from previously treated tuberculosis.[7,8]

All participant included in this study were young males with mean age of 26.5years (range: 20–39) with no other comorbidities as all of them were serving personnel. The age distribution was similar to the study done in Indonesia,[14] a high burden setting where the mean age of the patients was 30.6, as tuberculosis affect the economically productive age group. Selected participants were new cases of pulmonary tuberculosis having completed 2 months of intensive phase of treatment and were sputum smear negative. The rationale for including PRP along with chemotherapy at the end of 2 months was based on a previous study,[14] which showed improvement in the lung function parameters, FEV1 and FVC from baseline to end of 2 months. Initially, 39% of patients had moderate to severe impairment at baseline and 24.6% of these patients had moderate to severe impairment at end of treatment. The aim of our study was to determine if PRP introduced after 2 months of intensive phase treatment had a role in preventing or decreasing the residual impairment at the end of treatment. The concept of PR in pulmonary tuberculosis is not new. In a study done by Carrie Chapman in 1956,[18] the authors introduced a formalized system of dynamic exercises in the last 2 months of treatment of tuberculosis along with chemotherapy with the aim of returning the patient to his previous job immediately on discharge from hospital. 88/118 patients in the study could return to their full activity work at end of treatment. In the late phase of the same study between 1960–1963, a dynamic physical exercise program was instituted early along with chemotherapy. 155/267 patients returned to their work after discharge. This study changed the concept of prolonged rest and minimum exercise in treatment of tuberculosis patients.

In our study, we incorporated a PRP starting after completion of the intensive phase and continuing up to 12 weeks along with the pharmacological treatment of tuberculosis. This study had 2 parts. First part was to study the efficacy of a 12-week PRP on the pulmonary function, exercise capacity in terms of 6MWD and HRQOL compared with baseline parameters. The second part of the study compared the effect of the PR in the IG (the group undergoing the PRP) against an age matched group (CG) of similar patients of pulmonary tuberculosis undergoing treatment after the intensive phase but not undergoing the PRP.

There is no clear consensus on the duration of PRP. The duration used in various studies range from 4 weeks to 12 weeks. In a study by Ando et al[7] comparing the effect of PR in patients with post-tuberculosis lung disorder and COPD, the authors used a PRP of 9 weeks duration. Previous studies have shown that a minimum of 8 weeks of PR is required to achieve an effect on exercise performance and quality of life.[19]

At the end of 12 weeks of PRP, both IG and CG showed a statistically significant change in FEV1 and FVC compared with baseline values, but the change in FEV1 in IG (0.239L) was more as compared with CG (0.041L) and also significant. Findings were similar to a study by Grass et al [20] in which they assessed the effectiveness of a 6-week home-based PRP on lung function and HRQOL.

Exercise capacity measured by 6MWD showed a significant change from baseline to end of 12 weeks in both groups, but the change in IG was more as compared with CG (134 m vs 58.45m). The difference in 6MWD between the 2 groups was also significant. The improvement in exercise capacity after PR has been shown in previous studies.[20] Another study by Betancourt et al[21] showed an increase of 6MWD after 8 weeks of pulmonary rehabilitation in patients with post-tubercular sequelae. In a prospective non-randomized trial of 9 weeks conducted by Ando et al in Japan[7] after the PR program, there was significant improvement in 6MWD (42 m vs 47 m) in post-tubercular vs COPD group, respectively. There was no statistical difference between the 2 groups in terms of difference in SGRQ score after 12 weeks. These findings were similar to the findings of the study by Grass et al[20] where there was no statistically significant difference between the IG and CG in the quality of life score collected by EQ5D questionnaire. According to the ATS statement on SGRQ,[22] there was a mean change score of 12 units for very efficacious treatment. In this study although there was no statistically significant difference in SGRQ score between the 2 groups, there was a difference of 12.9 in the IG between baseline and at end of 12 weeks of Pulmonary rehabilitation, which signifies a highly efficacious treatment.

The findings of this study were similar to few other studies[23,24,25] which show the benefit of a PRP along with antitubercular treatment in improving residual pulmonary impairment.

This study has limitation of being a single center study. Further multicentric randomized control trials are needed.

Conclusion

A structured PRP of 12 weeks duration incorporated along with the treatment is an effective intervention in patients of pulmonary tuberculosis. Timely incorporation of PR along with treatment of pulmonary tuberculosis shows a significant improvement in pulmonary function and exercise tolerance.

Disclosure of competing interest

The authors have none to declare

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