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Research Article

COMPARISON OF DEMOGRAPHIC, LABORATORY PARAMETERS AND CLINICAL OUTCOMES AMONG TUBERCULOSIS PATIENTS WITH AND WITHOUT HYPERTENSION IN KANPUR AT TERTIARY CARE TEACHING HOSPITAL

Yatindra Kumar *[1], Parimalakrishnan. S [2], Md Mujahid [3], Irfana Sihab [2] and Seo Singh Pratap [4]
[1]Department of Pharmacy, GSVM Medical College, Kanpur, UP, India
[2]Department of Pharmacy, Annamalai University, Annamalai Nagar, TN, India
[3]Department of Pharmacy, Integral University, Lucknow, UP, India
[4]Department of Pharmacology, GSVM Medical College, Kanpur, UP, India
*Corresponding Author Email: yk.gsvm@gmail.com

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ABSTRACT

Background: Tuberculosis (TB) is a major global health problem and one of the top 10 causes of death worldwide. Aim: To compare the demographic characteristics, laboratory parameters and clinical outcomes of TB patients with and without hypertension (HTN) at a tertiary care teaching hospital. Methodology: A prospective cross-sectional study involving 220 patients divided into two groups with 95 patients from group I without HTN and 125 patients from group II with HTN. The study was conducted in the outpatient department of TB and chest medicine ward in a tertiary care teaching hospital. Results: The demographic data shows that males were affected. The economic status was similar in a group with Group I including 55%, 29.4% & 14.6% of subjects from poor, middle and rich economic status respectively and group II including 56.8%, 26.4% and 16.8% of subjects from poor, middle and rich economic status respectively. The study shows that alcohol consumption is a major risk factor in both groups. Chest X-ray, Mantoux test and sputum test was done almost for all subjects. Conclusion: From the present study we conclude that among selected demographic parameters and metabolic disorders were higher among patients with TB and HTN when compared with TB alone group. Smoking is the major risk factor-induced significant changes in functions of pulmonary and cavitary among both the group patients. The therapeutic goal was achieved for the group is attained faster when compared with the other group of patients, but both groups treatment was above 85% against the WHO statement. Adherence to therapeutic regimen was found to be satisfactory.

Keywords: Tuberculosis, Chest X-ray, Cavitary, Miliary disease, Cavitations

INTRODUCTION

Tuberculosis is an infectious disease and caused by bacillus *Mycobacterium tuberculosis* (MTB) which is a part of a complex of organisms including *Mycobacterium bovis* (reservoir cattle) and *Mycobacterium africanum* (reservoir human). It typically affects the lungs (pulmonary TB) but can also affect other sites (extrapulmonary TB)[1]. *Mycobacterium tuberculosis* is an obligate, pathogenic, rod-shaped and non-motile organism belonging to the family *Mycobacteriaceace.* It is an aerobic organism, this bacterium requires oxygen to grow, and divide s every 15-20 hours. It is a treatable, communicable disease has two phases – latent infection and active disease[2]. One of the chronic granulomatous infectious diseases is Tuberculosis. *Mycobacterium tuberculosis* bacilli infection occurs whenever a healthy population inhales few droplets. TB advancements through three different phases; Phase I is primary TB – Caseating of granulomas; Phase II is Post-primary bronchogenic and Phase III is effect period[3].

TB is the ninth leading cause of death worldwide and the leading cause of a single infectious agent, ranking above HIV/AIDS. In 2016, there were an estimated 1.3 million TB deaths among HIV-negative people (down from 1.7 million in 2000) and an additional 374 000 deaths among HIV-positive people[4]. An estimated 10.4 million people fell ill with TB in 2016: 90% were adults, 65% were male, 10% were people living with HIV (74% in Africa) and 56% were in five countries: India, Indonesia, China, Philippines, and Pakistan. Globally, the TB mortality rate is falling at about 3% per year. TB incidence is falling at about 2% per year[5].

According to the recent studies, WHO TB statistics for India for 2016 give an estimated incidence figure of 2.79 million cases of TB for India. The incidence of TB has reduced from 289 per lakh per year in 2000 to 217 per lakh per year in 2015 and the mortality due to TB has reduced from 56 per lakh per year in 2000 to 36 per lakh per year in 2015. The report highlighted that underreporting and underdiagnosis of TB cases continue to be a challenge, especially in countries with large unregulated private sectors and weak health systems, including India. India has the highest burden of both TB and MDR TB based on estimates reported in Global TB Report 2016. An estimated 1.3 lakh incident multi-drug resistant TB patients emerge annually in India which includes 79000 MDR-TB Patients estimates among notified pulmonary cases. India bears the second highest number of estimated HIV associated TB in the world. An estimated 1.1 lakh HIV associated TB occurred in 2015 and 37,000 estimated number of patients died among them[6,23]. The aim of the present study is to compare the demographic characteristics, laboratory parameters and clinical outcomes among the tuberculosis patients with and without hypertension in Kanpur at a tertiary care teaching hospital.

MATERIALS AND METHODS

The present is to study a prospective cross-section design. The study protocol was approved by the institutional ethics committee

of the hospital and obtained informed consent from all patients prior to enrolment. The study was conducted to the Declaration of Helsinki. The study was conducted in the OPD of Department of TB and Chest and medicine ward of a tertiary care teaching hospital located in Uttar Pradesh. The duration of the study was 12 months from June 2017 to July 2018. For all the patients'socio-demographic details like age, gender, place of residence, social habits like smoking, alcohol consumption, status of marriage, economic and occupation status whereas clinical parameters such as their major complaints, weight loss, hemoptysis, and decreased appetite were recorded, interpreted and analyzed. Inclusion criteria for the selection patients were: (i) patients >21 years of age with tuberculosis (ii) patients willing to participate and providing consent. Then the patients were divided into two groups as follows (a) Group I: TB patients without hypertension and (b) Group II: TB patients with hypertension. Further TB was diagnosed byAFB positive in sputum smear: either more than 2 sputum smear examination should give positive for AFB or one sputum smear with positive for AFB and radiological abnormalities with active tuberculosis[22]. All patients were subjected to the following investigations: (i) total blood count, (ii) complete biochemistry,(iii) lung function test, (iv) urine examination, (v) Chest X-ray, (vi) electrocardiogram, (vii) ultrasound sonogram abdomen, (viii)AFB sputum culture, (ix) blood pressure (x) blood glucose level, (xi) creatinine level and (xii) forced expiratory volume in first second (FEV_1).

Measuring of CXRs

CXRs were reviewed and measured by a specialist having experience in interpretation of TB radiographs and recorded in a standardized form. CXRs were reviewed and measured for film quality and different following aspects severity of disease was (i) normality of film like unilateral or bilateral disease (ii) disease severity was scored as low (≤ 1/5 or ≤ 1/2 of one lung field with densed or diffused abnormalities), mild (≤ 1/2 or ≤ 1 of one lung field with densed or diffused abnormalities) and high (abnormalities ≥ 1).

Third, a zone score was included for which each lung was divided into three equal zones and the score was based on the number of zones that were diseased. Abnormalities on the border of two zones were counted as a two-zone disease. The scoring of cavities resembled that described in the Madras Tuberculosis Prevention Trial[7], which included a category for ill-defined cavities for those whose contour could not be traced for at least three quarters of the perimeter of the cavity, with the a priori intent to exclude ill-defined cavities from analysis. Cavity size in mm was recorded separately[8].

Later, spirometric evaluation was performed by using portable spirometer and a Spirometric procedure was done according to ATS/ERS recommendation for standardization of lung function testing[9,23]. Patients were identified with post-bronchodilator FEV1 (Forced Expiratory Volume in the first second) <0.7 were considered and included in the final analysis as this value indicates the cut-off for the diagnosis of obstructive airway disease as per GOLD standard guideline. The present study was approved by the GSVM Medical College Ethics Committee was approved the protocol (Ref. No.: ND3255 ethics/ 2017; dated 20th July 2017). The present study was carried out as per International conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP).

Statistics

All values are expressed either in mean ± standard deviation or as a percentage (%). Data were analyzed using the program SigmaStat for Windows. Parameter differences among the 2 groups were analyzed by using one-way ANOVA Test and Kruskal–Wallis test for normally and non-normally distributed variables by applying Tukey's test and Bonferroni corrected Mann–Whitney U-test respectively for post hoc analysis. For the sociodemographic comparison, Chi-square test or Fisher's exact test was used as appropriate. A value of $p < 0.05$ was accepted as statistically significant.

RESULTS

A total number of subjects enrolled in this study was 220 and they were divided into two groups. 95 and 125 patients were allotted in group I and II respectively. 70% and 76% of male subjects were participated in the group I and II respectively, whereas females were 30% and 24% in the group I and II respectively. The average age among the subjects was 46.28±11.37 years and 55.34±12.05 years in the group I and II respectively. 66% and 70.4% of subjects in the group I and II were from rural respectively, while 34% and 29.6% of subjects in the group I and II were from urban respectively. In the group I, 14.7%, 25.3% and 10.4% of subjects were having the habits of smoking, alcoholics and having both habits respectively and in group II 14.4%, 25.6% and 10.4% of subjects were having the habits of smoking, alcoholics and having both habits respectively. The subjects reported of having a family history of tuberculosis was 25.3% and 94.7% were married in group I and in group II family history of tuberculosis was found to be 36.8% and 96.8% were married.

The economic status was almost similar in both the groups. In group I 55%, 29.4% and14.6% of subjects belonged to poor, middle and rich economic status respectively, while in group II 56.8%, 26.4% and 16.8% of subjects belonged to poor, middle and rich economic status respectively. In occupation status, more subjects in group I was having white collar jobs; and in group II many of them were daily wage workers. In group I 2.3% subjects were students, 14.7% subjects were housewives, 53.6% subjects work as daily wage workers, while 29.4% subjects have white collar jobs; and in group II 4.8% subjects were students; 18.4% subjects were housewives. 61.6% of subjects work as daily wage workers, while 15.2% of subjects have white collar jobs.

In both groups, most of them complained of having a cough and fever for <1 week (GI: 51%; GII: 49%). In group I 25.2% of them had for 1-3 weeks, 16.8% of them had for nearly from 3 weeks to 1 year, and 7% of them had for more than one year; and in group II 31% of them had for 1-3 weeks; and 25% of them had for nearly from 3 weeks to 1 year. In both groups most of the subjects had weight loss (G-I: 62%; G-II: 58.4%), followed by having decreased appetite (G-I: 23%; G-II: 936.8%). In group I 33.7% of them had complaints of hemoptysis, and in group II 38.4% of them had complaints of hemoptysis.

In group I 37% of them had SBP between 120-130 mmHg & 63% of them had SBP between 131-140 mmHg; 48.4% of them had DBP between 80-85 mmHg & 51.6% had between 86-90 mmHg of DBP. In group II 46.4% of them had SBP between 140-160 mmHg & 53.6% had SBP above 160 mmHg; 52% had DBP of 90-100 mmHg & 48% had DBP above 100 mmHg. Group II has higher SBP & DBP than group I. In both groups Chest X-ray and Mantoux test was done in all subjects (100%). Sputum for acid-fast bacillus was taken in most of the subjects (G-I: 93.7%; G-II: 92%). Electrocardiogram was done in most of the subjects (G-I: 94.7%; G-II: 97%). Ultrasound sonogram abdomen (G-I: 78%; G-II: 80.8%), lung function test (G-I: 79%; G-II: 67%), Urine examination (G-I: 69%; G-II: 76%), Complete biochemistry test (G-I: 62%; G-II: 50.4%), & total blood count (G-I: 43%; G-II: 45%) was done.

The following comorbidities were observed in both groups: COPD was about 12.6% and 14% in GI and GII respectively, whereas anaemia was observed 39% and 24% in GI and GII respectively while diabetes mellitus was seen in 44.2% and 29%

of the population in GI and GII respectively. The rheumatoid arthritis was present in 26% and 18% of patients in GI and GII respectively but chronic renal failure was noticed in 10.5% and 7.2% of patients in GI and GII respectively and hypothyroidism was in 6.3% and 6.4% GI and GII respectively. 100% of subjects were having hypertension as one of the comorbidities among the G II subjects and no subjects were having hypertension as comorbidity between GI subjects. The data are presented in Table 1 as a percentage.

Table 1: Demographic, clinical and laboratory parameters among the 2 groups of patients

Parameters	Group I (N = 95) %	Group II (N = 125) %	P – Value
Mean Age (Years)	46.28±11.37	55.34±12.05	<0.001**
Gender (Male/ Female)	70/ 30	76/ 24	0.21***
Type of Residence (Rural/ Urban)	66/ 34	70.4/ 29.6	0.11***
Smoking (Yes/ No)	14.7/ 25.3	14.4/ 25.6	<0.001**
Alcohol (Yes/ No)	12.6/ 18	12/ 19.2	
Smoking & Alcohol (Yes/ No)	10.4/ 19	10.4/ 18.4	
Family History (Yes/ No)	25.3/ 74.7	36.8/ 63.2	<0.001**
Married (Yes/ No)	94.7/ 5.3	96.8/ 3.2	
Economic Status			<0.001**
Lower class	55	56.8	
Middle class	29.4	26.4	
Upper class	14.6	16.8	
Occupation,			<0.001**
Daily wage workers	53.6	61.6	
Students	2.3	4.8	
Housewives	14.7	18.4	
White collar job	29.4	15.2	
Complaints			<0.001**
Cough& Fever (Yes/ No)			
< 1 week	51	49	
1–3 weeks	25.2	31	
3 weeks – 1 year	16.8	20	
> 1 year	7	0	
Hemoptysis (Yes/ No)	33.7/ 66.3	38.4/ 61.6	
Weight loss, (Yes/ No	62/ 38	58.4/ 41.6	
Decreased appetite	23/ 77	36.8/ 63.2	
Clinical Characteristics (Yes/ No)			<0.001**
SBP	37/ 63†	46.4/ 53.6‡	
DBP	48.4/ 51.6 ††	52/ 48 ‡‡	
Total Blood Count	43/ 57	45/ 55	
Complete biochemistry	62/ 38	50.4/ 49.6	
Lung Function Test	79/ 21	67/ 33	
Urine examination	69/ 31	76/ 24	
Chest X-ray	100/ 0	100/ 0	
Electrocardiogram	94.7/ 5.3	97/ 3	
Ultrasound Sonogram abdomen	78/ 22	80.8/ 11.2	
Sputum for Acid Fast Bacillus	93.7/ 6.3	92/ 8	
	100/ 0	100/ 0	
Comorbidities (Yes/ No)			<0.001**
HTN	0/ 100	100/ 0	
COPD	12.6/ 87.4	14/ 86	
Anaemia	39/ 61	24/ 76	
Diabetes mellitus	44.2/ 55.8	29/ 71	
Rheumatoid arthritis	26/ 74	18/ 82	
Chronic renal failure	10.5/ 89.5	7.2/ 92.8	
Hypothyroidism	6.3/ 93.7	6.4/ 93.6	

** P – Value is based on one way ANOVA test; *** P – Value is based on Chi-square test and/ or Fisher's test. Groups with significant differences according to the post hoc Tukey's test and Bonferroni corrected Mann–Whitney U-test. † (≤ 140 mmHg); † † (≤ 90 mmHg); ‡ (≥ 140 mmHg); ‡ ‡ (≥ 90 mmHg)

Table 2: Clinical characteristics and radiographic comparison between TB patients with and without hypertension

Parameters	Group I (N = 95), %	Group II (N= 125), %
Chest X-ray (Yes/ No)	85/ 10	111/ 24
Disease severity		
Low	19	62
Mild	67	55
High	09	05
CXR weighted score	87	112
Consolidation	75	103
Cavitations§	41	99
Fibrosis	38	65
Nodules	66	91
Miliary disease	70	117
Effusion	93	123
Clinical characteristics		
BCG scar	23	41
Duration of a cough, median in weeks (range)	10 (5 – 30)	34 (5 – 30)
Tuberculin skin test	72	100
BMI, median (range)	21.5 (20 – 23)	22.8 (21.7 – 23.9)
FEV_1	1.35±0.25	1.12±0.19
A score of smear grade at diagnosis		
None or 0	16	22
Scanty or 1+	52	82
2+	21	13
3+	06	08

Chest X-ray was taken in most of the subjects in group I (89%) and group II (88.8%). The severity of disease was measured among the subjects. The low level of infection in group I and II was found to be 20% and 49.6% respectively, whereas the mild level was observed in 70.5% and 44% in group I and II respectively while in group I and II the high level of infection was noticed in 9.5% and 6.4% of subjects. Chest X-ray weighted score was high in group I (91.7%) than in group II (89.6%). The consolidation, cavitations, fibrosis, nodules and military was reported high in group II (82.4%, 79.2%, 52%, 72.8% and 93.6%) than in group I (78.9%, 43.1%, 40%, 69.4% and 73.6%).

Pleural effusion was high among the subjects participated in both the groups (G-I: 97.8%, G-II: 98.4%). BCG scar was mostly seen among the subjects of group II and I as 32.8% and 24.2% respectively. The median of a duration cough per week ranging between were 5 – 30 in group I (10.5%) and group II (27.2%). Tuberculin skin test was done for 75.7% of subjects in group I and 80% in group II. The average median of BMI ranging 20-23 was 22.6% of subjects in group I and 18.2% in group II. The forced expiratory volume in one second was measured as 1.35±0.25 and 1.12±0.19 in group I and II respectively. The score of smear grade at diagnosis was high in subjects having scanty or 1+ score (G-I: 54.7%; G-II: 65.6%) followed by 2+ score (G-I: 22.2%; G-II: 10.4%) and 3+ score (G-I: 6.3%; G-II: 6.4%) but 16.8% in group I and 17.6% in group II reported for none (or) 0 scanty score.

DISCUSSION

In the present study, from total 220 tuberculosis subjects 125 subjects were considered to have hypertension. The demographics data studied were; Males were the most affected subjects than females in both the groups in contrast to the study conducted by Ayaz *et al,* 2012, where females were more prone to develop the condition[10]. The mean age was high in group II. Most of the subjects are from rural areas than in urban areas in both groups. The increase in the number of alcohol consumption in both groups proves that alcohol consumption is one of the risk factors in developing the condition. In both the groups, the economic status of the most of the subjects belonged to the poor class, followed by middle class and rarely rich class subjects which show that the prevalence of the condition is more frequent in poor economic conditions. In occupation status, more subjects in group I was having white collar jobs; and in group II many of them were daily wage workers. In both groups most of them complained of having cough and fever for <1 week; some subjects had complaints from 1-3 weeks and few subjects had for nearly from 3 weeks to 1 year, and very few subjects had complaints for more than 1 year. Most of the subjects reported to have weight loss followed by decreased appetite and some subjects had complaints of hemoptysis in both groups. Group II has higher SBP and DBP than group I. In both groups Chest X-ray and Mantoux test was done in all subjects. Sputum for acid-fast bacillus, electrocardiogram, ultrasound sonogram abdomen, lung function test, urine examination, complete biochemistry test, and total blood count test was done and there was no significant difference between both the groups. The comorbidities in group II subjects were reported having hypertension followed by diabetes mellitus, then anaemia, rheumatoid arthritis, and few COPD, chronic renal failure and a very few subjects having hypothyroidism disorder; while in group I no subjects were considered to have hypertension; but had diabetes mellitus, anemia, rheumatoid arthritis, COPD and chronic renal failure and hypothyroidism.

The level of infection was mild in group I and low in group II subject. There is no significant difference observed in Chest X-ray weighted score, the consolidation, presence of fibrosis, military tuberculosis, and presence of pleural effusion. The cavitations were reported high in group I than group II. The median of a duration cough per week ranging between was high in group II. Tuberculin skin test was done for both the groups. The forced expiratory volume in one second was measured as 1.35±0.25 and 1.12±0.19 in group I and II respectively. The score of smear grade for both the group at diagnosis was high in subjects having scanty or 1+ score followed by having 2+ score and 3+ score and 0 scanty but in group II reported for none (or) 0 scanty score. The present study explains the socioeconomic and clinical parameters of patients with TB and without TB about two year's period in a moderate incidence area for TB, with an average economic status population. The present study key findings are: (i) in this study site TB is largely a disease in subjects who live with low economic status (55.9%). Subjects in high economic status are significantly less (15.7%); (ii) Prevalence of co-infection was higher among the TB subjects with hypertension group rather than other group of subjects in the present study whereas in the literature, our country showed 91.10 % and Southeast Asia regions have shown 93.42% of prevalence of co-infection; (iii) TB subjects with HTN was common (56.8%) and

more especially in males; (iv) however, cavitary TB and smoking have direct relationship in adults when compared with elderly patients; (v) Sputum culture test was done in 89 and 115 (93.7% & 92%)to confirm presence of bacteria by bronchoscopy in group I and II subjects respectively; (vi) Out of 95 and 125 subjects in group I and II around (25.78%) and (36.49%)was observed severe side effects respectively. WHO criteria to new sputum smear-positive pulmonary cases only, the treatment success rate for the 1999 – 2017 period was 83%, i.e. it is near to the 85% success target[11].

In the present study, the risk of developing cavitary TB was higher among smokers than the nonsmokers in both groups our findings were similar with the previous report[12]. Clinical signs and symptoms get altered when there is an increase in the rate of positive sputum culture, zone involvement, cavitary TB and military disease are due to some factors like smoking, hypertension etc. Smoking affects the clinical manifestations of TB by notably increasing the occurrence of upper zone involvement, cavitary and miliary disease, and rate of positive sputum cultures[13,14,15]. Suggested mechanisms include decreased immune response and decreased the production of TNFα by macrophages[16]. Down-regulation of macrophage TNF-α in the lungs may render the patient more susceptible to the development of progressive and severe disease. This mechanism was already described with the use of anti-TNFα treatment[17].

In our study, miliary TB (73.6% and 93.6%) was reported high than cavitary TB (43.1% and 79.2%) in both the groups. Clinical and radiological presentation of pulmonary TB in subjects is frequently atypical, with a more frequent involvement of lower and middle lobes, of miliary patterns, and, in several studies, less frequent cavitary lesions[18,19,20], although this latter observation remains controversial. Bacteriological confirmation of TB was obtained by tuberculin skin test of all pulmonary TB. An earlier study which has been conducted in south India in 2014 showed a high proportion of Tuberculin skin test positive (91%) and the presence of BCG scar (62.7%). In our study, both tuberculin skin test and presence of BCG scar were reported high in group II (80% and 32.8%) than in group I (75.7% and 24.2%).

A primary outcome of the study was to achieve goals of TB treatment. Abhijit Mukherjee, Rupak Singla et al, 2014, reported 72.8% of sputum smear-positive pulmonary TB, wherein this study the result of sputum smear-positive pulmonary TB was higher having 83.2% and 82.4% in group I and group II respectively. The same study reported delayed presentation, and improper diagnosis under field conditions in smear-negative cases are responsible for the decreased incidence of a favorable outcome in low HIV areas. They recommend a more intense training of medical students' involvement in the RNTCP[21-23].

CONCLUSION

TB patients are from younger productive aged living in rural having a high incidence of extra-pulmonary involvement. Due to the high prevalence of HTN among subjects living in poor economic status, is an additional key risk factor to cause a delay in the outcome. Subjects having smear +ve for TB, 85% of WHO therapeutic goal was attained successfully. Nearly 40% of subjects were lost follow up and remaining was having cough and fever for more than 20 days. There is a good relationship between cavitary TB and smoking as well as the influence of smear –ve TB needs further examinations. The present study showed that the level of adherence to therapeutic was high and resistance is poor. Few recurrent subjects experienced restriction of airflow regardless of smoking habits was observed treating them become difficult and complexed. In the end, we conclude that early diagnosis and proper treatment should be initiated in order to reduce the post – TB complications like fibrosis and scars, which will further deteriorate lung functions.

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