



DEMOGRAPHIC AND CLINICAL ASPECTS OF TUBERCULOSIS: A CASE SERIES OF PATIENTS FROM IN-PATIENT DEPARTMENT OF A HOSPITAL

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ABSTRACT

Controlling tuberculosis in India is a tremendous challenge. The disease is a major barrier to social and economic development. Based on the current scenario, the present observational prospective study was designed for 63 patients with tuberculosis admitted in in-patient department of a government general hospital in four months. Case sheets and laboratory reports of patients were collected and noted for evaluation. The study included patients who were all having active disease and absence of HIV infection. The follow-up of the patients was done every day. The case sheets of the patients revealed their age distribution, gender, body weight distribution, history of illness and previous illness, social habits, common and uncommon signs and symptoms, diagnostic tests performed, treatment therapy provided and adverse effects. Early identification of TB cases and the effective use of the first line drugs were the primary goals of the department. The common clinical features observed in the patients as well as the therapy provided by the physicians was typical and as per the Revised National Tuberculosis Control Programme of Government of India. Non-adherence, drug resistance, extra-pulmonary disease and severe contaminant disease states were not observed.

Keywords Tuberculosis, In-patient, Hospital, Demography, Therapy.

INTRODUCTION

Tuberculosis (TB) remains a leading infectious killer globally. TB is caused by *Mycobacterium tuberculosis*, which can produce either a silent, latent infection or a progressive, active disease. Left untreated or improperly treated, TB causes progressive tissue destruction and, eventually, death. India is the highest TB burden country with World Health Organization statistics for 2011 giving an estimated incidence figure of 2.2 million cases of TB for India out of a global incidence of 8.7 million cases. Most of the TB statistics for India come from the government Revised National Tuberculosis Control Programme (RNTCP) which was started in 1997, and then expanded across the country. In 2012 India declared TB to be a notifiable disease meaning that with immediate effect all doctors, caregivers and clinics treating a TB patient had to report every case of TB to the government.^{1,2}

Once infected with *M. tuberculosis*, a person's lifetime risk of active TB is approximately 10%. The onset of TB may be gradual, and the diagnosis may not be considered until a chest radiograph is performed. Unfortunately, many patients do not seek medical attention until more dramatic symptoms, such as frank hemoptysis, occur. Expectoration or swallowing of infected sputum may spread the disease to other areas of the body.³

The treatment of active TB requires the use of multiple drugs. There are two primary anti-tuberculosis drugs, isoniazid and rifampin, with the rest of the drugs having specific roles. Isoniazid and rifampin should be used together whenever possible. The standard TB treatment regimen is isoniazid, rifampin, pyrazinamide, and ethambutol for 2 months, followed by isoniazid and rifampin for 4 months, for a total of 6 months of treatment. If susceptibility to isoniazid, rifampin, and pyrazinamide is shown, ethambutol can be stopped at any time.^{1,4}

Based on the current scenario, the present observational prospective study was designed for 63 patients with tuberculosis admitted in a government general hospital.

Patients diagnosed with tuberculosis were studied to collect the socio-demographics and therapeutic data. The follow-up of the patients was done every day.

MATERIALS AND METHODS

Study design

The present study was a prospective observational study.⁵

Study site

The study was conducted in the in-patient department (IPD) in Department of Medicine, TB and Chest of Sri Venkateswara Ramnarain Ruia (SVRR) Government General Hospital (a 720-bedded multispeciality hospital), Tirupati, Andhra Pradesh.

Study duration

The period of study was for four months, i.e. November 2012 to February 2013.

Study criteria

Inclusion criteria

Tuberculosis patients (i.e. both recently diagnosed and recurrent TB patients) treated with standard drugs with or without comorbidities in any age group were included in the study.

Exclusion criteria

Tuberculosis patients visiting out-patient department (OPD) and patients visiting TB and Chest Ward with other disease complaints like asthma were excluded from the study.

Sources of data

Case sheets and laboratory reports of patients were collected and noted for evaluation.

Study procedure

Case sheets of in-patients including their treatment charts and laboratory reports were reviewed for evaluating the therapy of tuberculosis patients. Patient consent and permission from

the head of the department for the study were obtained before collecting the required data. The age group and gender of patients affected by tuberculosis were noted. Also analysed were the weight loss in patients and presence or absence of HIV. The common and uncommon signs and symptoms as well as their duration were observed. Medical history of both patients and family were documented. Smoking, drinking and other social habits of patients were noted. Also analysed were the physical examinations for the diagnosis of the disease such as blood pressure, lung capacity, pulse rate, etc. and laboratory reports like sputum test, blood tests, blood glucose levels, ultrasound, etc. to confirm the disease. The primary side effects of the drugs which were observable in patients were documented. The rationality in the treatment approach was determined by comparing with the standard established guidelines.^{6,7}

Statistical methods

The data was tabulated and analysed using GraphPad Prism software, v. 5.01.

RESULTS AND DISCUSSION

The present study was a prospective study of patients infected with tuberculosis in in-patient department in a multi-specialty government hospital. The case sheets of patients were used to evaluate the various clinical features of this infectious disease.

Evaluation of age group and the mean age of patients

The age group distribution of patients (Figure 1) revealed that most patients infected with the disease belong to middle age group. There were no patients below 10 years and above 90 years of age. Significant numbers of patients (Table 1) were in the age group of 31 – 40 years (22.22%) and 41 – 50 years (20.63%). The mean age was found to be 50.94±2.15 years.

Table 1: Evaluation of percentage age distribution and mean age of tuberculosis patients

0 – 10	11 – 20	21 – 30	31 – 40	41 – 50	51 – 60	61 – 70	71 – 80	81 – 90	91 – 100	Mean age
0	3.17	9.52	22.22	20.63	19.05	11.11	11.11	4.76	0	50.94 ± 2.15

Table 2: Evaluation of history of illness and previous illness of tuberculosis patients

S.No.	Reg.No	History of illness	Previous illness
01	31	Swelling in left side of lung, fever, cough.	Carcinoma, vomiting, chest pain, bowel restriction, breathlessness.
02	293	High grade intermittent fever, nausea, vomiting.	Cough, sputum copious, breathlessness.
03	39294	Breathlessness, cough.	Fever, hypertension, diabetes mellitus.
04	39909	Left side chest pain, non-productive cough, breathlessness, fever.	Bowel and bleeding habits.
05	39361	Non-productive cough aggravated by lying on vertical position.	Fever, vomiting, breathlessness.
06	236	Swelling, gripping chest pain, non-productive cough.	-
07	39014	Arrhythmia, whitish cough, non-foul smelling, scanty.	Chest pain, breathlessness, wheezing.
08	39295	High grade fever.	Productive white cough, scanty.
09	40010	Breathlessness occasionally, loss of weight.	Loss of appetite.
10	38437	Cough with diurnal variation, white, foul smelling.	-

Table 3: Evaluation of physical examinations and laboratory reports of tuberculosis patients

S.No.	Reg.No	Physical examinations	Laboratory reports
01	31	B.P. – 120/80 mm, Pulse – 92/min, PT – fair, Cough – +	Blood sugar – 89mg/dl, Sputum test – +, differential count, Blood urea, Hemoglobin, Bleeding time, Clotting time, Erythrocyte Sedimentation Rate
02	293	B.P. – 100/60 mm, Pulse – 100/min, PT – coherent, Fever – +, Cough – +	Blood sugar – 90mg/dl, Sputum test – +, Serum creatinine – 1.6mg%, Total cell count, differential count
03	39294	B.P. – 110/80 mm, Pulse – 92/min, PT – coherent, Fever – +	Blood sugar – 86mg/dl, Sputum test – +, Serum creatinine – 1.5mg%, Erythrocyte Sedimentation Rate
04	39909	B.P. – 130/70 mm, Pulse – 115/min, PT – fair	Sputum test – +, Serum creatinine – 1.2mg%, Total cell count, Blood urea
05	39361	B.P. – 140/100 mm, Pulse – 84/min, PT – fair, Cough – +	Blood sugar – 28mg/dl, Sputum test – +, Serum creatinine – 1.0mg%
06	236	B.P. – 130/90 mm, Pulse – 98/min, PT – conscious	Sputum test – +, Total cell count, Ultra sound – chest-moderate/massive
07	39014	B.P. – 100/80 mm, Pulse – 112/min, PT – fair, Fever – +	Sputum test – +
08	39295	B.P. – 115/70 mm, Pulse – 100/min, PT – fair, Cough – +	Blood sugar – 102mg/dl, Sputum test – +, Serum creatinine – 0.9mg%
09	40010	B.P. – 120/80 mm, Pulse – 118/min, PT – fair, Fever – +, Cough – +	Sputum test – +
10	38437	B.P. – 140/100 mm, Pulse – 84/min	Sputum test – +.

Table 4: Evaluation of primary side effects and dose adjustment in renal impairment in tuberculosis patients

S.No.	Generic name of drugs	Primary side effects	Dose adjustment in renal impairment
01	Isoniazid	Clinical hepatitis, peripheral neuropathy, CNS effects, lupus like syndrome, hypersensitivity reactions.	No
02	Rifampin	Pruritus, rash, hepatotoxicity, GI problems (nausea, anorexia, abdominal pain), flu like syndrome, thrombocytopenia, renal dysfunction.	No
03	Rifabutin	Neutropenia, uveitis, GI symptoms, polyarthralgia, hepatotoxicity, rash.	No
04	Pyrazinamide	Hepatotoxicity, nausea, anorexia, rash, dermatitis, polyarthralgia, hyperuricaemia.	Yes
05	Ethambutol	Optic neuritis, skin rash, drug fever.	Yes
06	Streptomycin	Vestibular or auditory dysfunction, renal dysfunction, skin rash.	Yes

Table 5: Evaluation of first line drugs prescribed in treatment of tuberculosis patients

S. No.	Reg. No.	Generic name of drugs	Form and route of administration	Dose	Dose frequency
01	31	Isoniazid	Tablet (oral)	300mg	Thrice weekly
		Rifampin	Capsule (oral)	300mg	Thrice weekly
		Pyrazinamide	Tablet (oral)	150mg	Thrice weekly
		Ethambutol	Tablet (oral)	250mg	Thrice weekly
		Streptomycin	IV (Parenteral)	10mg	Thrice daily
02	293	Isoniazid	Tablet (oral)	300mg	Thrice weekly
		Rifampin	Capsule (oral)	300mg	Thrice weekly
		Ethambutol	Tablet (oral)	250mg	Thrice weekly
03	39294	Isoniazid	Tablet (oral)	300mg	Thrice weekly
		Rifampin	Capsule (oral)	300mg	Thrice weekly
04	39909	Isoniazid	Tablet (oral)	300mg	Thrice weekly
		Rifampin	Capsule (oral)	300mg	Thrice weekly
		Pyrazinamide	Tablet (oral)	250mg	Thrice weekly
05	39361	Isoniazid	Tablet (oral)	300mg	Thrice weekly
		Rifampin	Capsule (oral)	300mg	Thrice weekly
		Pyrazinamide	Tablet (oral)	250mg	Thrice weekly
		Ethambutol	Tablet (oral)	400mg	Thrice weekly

Table 6: Evaluation of antibiotics and drugs prescribed as combination therapy in tuberculosis patients

S. No.	Reg. No.	Generic name	Form and route of administration	Daily dose	Dose frequency
01	31	O2 inhalation/sos Duolon nebulizer	Gaseous(inhalation)	6 th hourly	Twice weekly
		Cycloserin	Tablet	8 th hourly 250mg	Twice weekly Twice daily
02	293	Kanamycin	IV (parenteral)	500mg	Once a day
03	39909	Amikacin	IM (parenteral)	500mg	Once a week
04	39361	Oxygen inhalation	Gaseous (inhalation)	14hrs/day	Once in a week
05	236	Levofloxacin	IV (parenteral)	500mg	Twice in a week

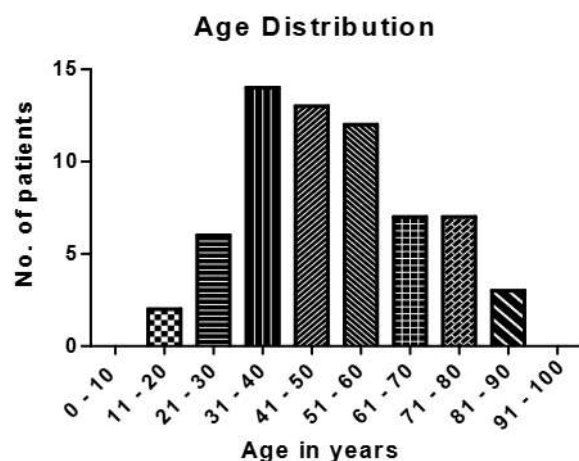


Figure 1: Graph showing age distribution of tuberculosis patients

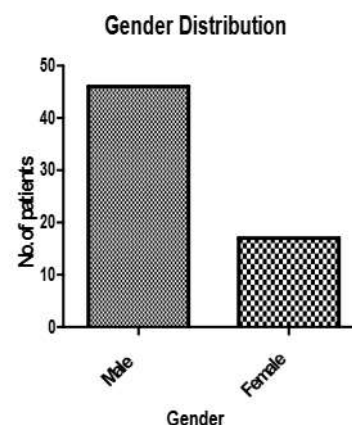


Figure 2: Graph showing gender distribution of tuberculosis patients

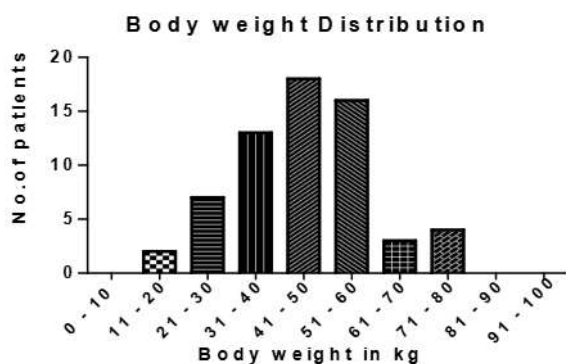


Figure 3: Body weight distribution of tuberculosis patients

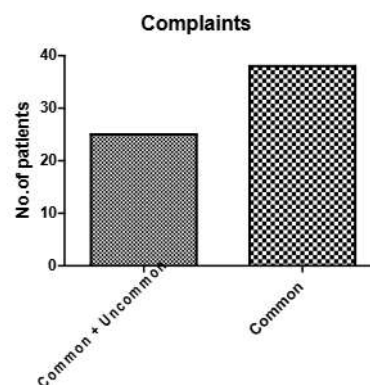


Figure 4: Graph showing common and uncommon complaints of tuberculosis patients

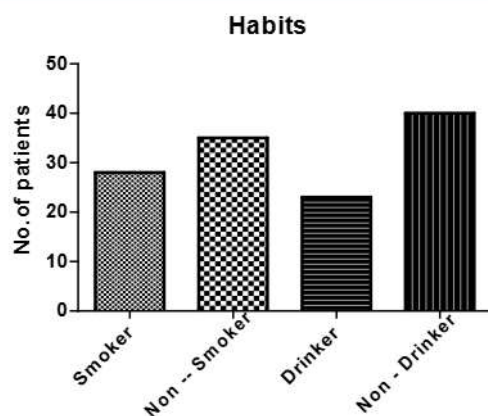


Figure 5: Graph showing smoking and drinking habits of tuberculosis patients

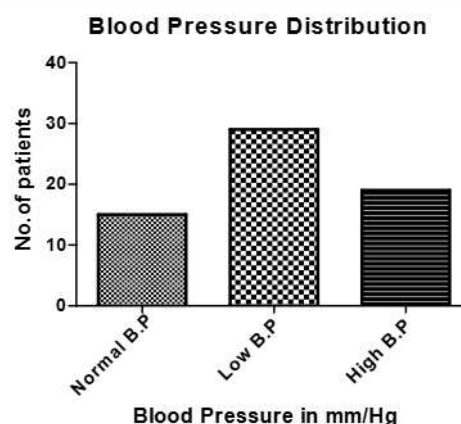


Figure 6: Graph showing blood pressure of tuberculosis patients

Evaluation of gender distribution of patients

The gender distribution study (Figure 2) revealed that maximum number of patients (73.02%) were males while only 26.98% patients were females. It showed that epidemiologically males were more prone to attack of the disease as compared to women due to various etiological factors.

Evaluation of presence of HIV infection in patients

The diagnosis for HIV revealed that there were no patients who were HIV positive. All the patients were free from HIV even though HIV increased the chances of occurrence of tuberculosis.⁸

Evaluation of body weight of patients

The body weight distribution (Figure 3) revealed that significant number of patients had less body weight (34.92%) which is usually a common clinical symptom in tuberculosis. The study also revealed that majority of the patients had body weight in the range 41–50 kg, which is below average weight range for adults.

Evaluation of common and uncommon complaints of patients

The evaluation of complaints (Figure 4) showed that commonly (60.32%) patients had symptoms of fever, cough, chest pain, breathlessness and loss of weight. It correlated with the usual symptoms of tuberculosis. Some patients (39.68%) had reported atypical symptoms like giddiness, vomiting, abdominal pain, etc. which may be due to side effects of the infection, or due to presence of other comorbid conditions. The duration of patients' complaints varied widely depending on the patient's health status with some reporting one week while some reported more than one month.⁹

Evaluation of history of tuberculosis and previous illness in patients

The evaluation of history and previous illnesses revealed that all the patients were prone to tuberculosis infection. The patients reported the common signs and symptoms of tuberculosis before actually contacting the active disease. History of illness showed that the patients probably had latent tuberculosis based on the presence of cough, sputum,

breathlessness, chest pain, etc. The results of 10 sample patients were revealed in Table 2.

Evaluation of social habits and family history of patients

The social habits (Figure 5) showed many patients were smokers (44.44%) and drinkers (36.50%) which were significant. Smoking is a common risk factor for tuberculosis, so they became more prone to infection. Also most of the patients had a mixed (non-vegetarian) diet. The study of family history revealed no correlation between it and occurrence of the disease. There were no cases of tuberculosis formed in family history.

Evaluation of physical examinations of patients

The physical examinations (Table 3, Figure 6) carried out for diagnosis such as blood pressure, pulse rate, fever and cough, and patient status were evaluated. The data revealed that most of the patients had low blood pressure (46.03%) while few had normal blood pressure (23.81%). Also it was found that all the patients had a high pulse rate, in some cases, more than 100, which indicated stress. Majority of the patient had both cough and high body temperature, which was common in tuberculosis. The patients were fair and in conscious state even though the blood pressure and pulse rate levels were abnormal. Table 3 revealed the data for 10 sample patients.

Evaluation of laboratory tests for diagnosis in patients

Table 3 showed the laboratory tests carried out for 10 sample patients. Laboratory tests commonly carried out for diagnosis included sputum test, blood sugar levels, serum creatinine and blood tests. All the patients had sputum test positive for the presence of bacteria. The blood sugar tests were done to check the presence of coexisting diabetes mellitus, which influenced the therapeutic regimen. Various hematological tests were performed for bleeding disorders, anemia, leucopenia or leukocytosis indicating the presence of infection.¹⁰

Evaluation of observable side effects of the first line drugs in patients

The side effects of the first line drugs were observed (Table 4). It was found that the drugs commonly exhibited effects like gastrointestinal disturbances like nausea, anorexia, etc and hypersensitivity reactions like dermatitis, rash, etc. other frequent adverse effects seen were hepatotoxicity, CNS

effects and renal dysfunction. The side effects primary was related to the dose and long term use of the drugs and was as per their labeling instructions. Rarely polyarthralgia, uveitis and hyperuricaemia were observed in patients. Due to the presence of renally impaired elderly patients dose adjustment was required for drugs pyrazinamide, ethambutol and streptomycin.^{11,12}

Evaluation of rationality of standard therapy regimen prescribed for treatment in patients

The treatment therapy of 5 sample patients prescribed was reported in Table 5. The generic name of first line drugs their form and route of administered daily dose and dose frequency were noted. The standard drugs used for treatment were isoniazid, rifampin, pyrazinamide, ethambutol and streptomycin, which were as per the WHO guidelines and Revised National Tuberculosis Control Programme (RNTCP) of Govt. of India. The drugs were prescribed in both oral and parenteral dosage form as per the condition of the patient. The dosage forms commonly used were tablets and capsules because of good patient compliance. The doses and dosage frequency were as per normal regimen. There was no discrepancy or deviation in the prescribed anti tubercular therapy regimen when compared with the standard guidelines for all the patients.^{3,8}

Evaluation of antibiotics and other drugs prescribed for treatment in patients

Antibiotics and other drugs prescribed as combination therapy of 5 sample patients was reported in Table 6. The commonly prescribed antibiotics to treat the infection were fluoroquinolones like levofloxacin, gatifloxacin etc, and aminoglycosides like amikacin, kanamycin etc. which have high efficacy rate. Oxygen inhalation was given to patients as and when needed. The antibiotics were administered in the form of both oral (tablets and capsules) and parenteral (intramuscular and intravenous) route. The daily dose and dose frequency were prescribed as per the body weight and status of the patients to reduce adverse effects. There was no discrepancy or deviation from the standard guidelines in the combination therapy.^{13,14}

Early identification of TB cases and the effective use of the first line drugs were the primary goals of the department. Non-adherence, drug resistance, extra-pulmonary disease and severe contaminant disease states were not observed. Directly observed treatment were done to improve compliance as many patients were poor and under privileged. Therapeutic

drug monitoring was done by the physicians to reduce the number of adverse effects.

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