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AN EPIDEMIOLOGICAL STUDY OF DRUG RESISTANT TUBERCULOSIS CASES REGISTERED UNDER DOTS PLUS CENTER IN A RURAL BASED TERTIARY CARE HOSPITAL

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Abstract

Background: Drug resistance in tuberculosis is a global problem and India is no exception to this. However, this rise is mainly among the previously treated cases as previous antituberculosis therapy is the single most important risk factor for the development of drug resistance. The worldwide prevalence of drug resistant tuberculosis is on the rise and multiple studies give varying data regarding the epidemiology of drug resistant tuberculosis. This study was taken up to determine the demographic profile of a patient, previous history of anti tubercular drug intake and pattern of drug resistant.

Design: Prospective observational study.

Methods and Materials: Patient who are Sputum positive, diagnosed drug resistant tuberculosis and fulfill the inclusion and exclusion criteria, admitted from March 2015 February 2016 in DOTS PLUS centre, BMCH, Burdwan. To accomplish the objectives, information was collected by personal interviews using pre-designed, pre-tested proforma. Data, so collected, was analyzed and tabulated using appropriate statistical software.

Results: More than 2/3rd were males and majority were in age group 18-55 years, educated up to primary level, living in overcrowded and ill-ventilated houses belongs to upper lower and lower class (IV & V) on Kuppuswamy's SES 2014. Initially almost all had pulmonary TB. At the start of category II, maximum number of patients was relapse cases. The prime cause being financial crunch and lack of knowledge. Resistance to both rifampicin and isoniazide (MDR) was found in more than 2/3rd of cases. 3 patients (3%) were reactive for HIV in the study.

Conclusion: In general even after considering so many diversified variables it could be stated that most of the patients perceived some degree of improvement in their condition following treatment.

Introduction

Tuberculosis (TB) is one of the oldest diseases known to mankind since time immemorial and continues to be a major public health problem even in today's modern world. It is a preventable and curable disease, but still million of people suffer every year and a number of them die from this disease, resulting in a heavy impact on social and economic development. Its causative organism Mycobacterium tuberculosis was one of the disease is clearly understood. A vaccine against tuberculosis has been available for close a century. Effective treatment against the disease has been available for sixty years. Yet the disease is close to its highest level ever and so, the World Health Organisation declared tuberculosis as a global public health emergency in 1993.(1-4) Tuberculosis primarily affect the lung but can affect part of the body such as intestine, bones, joints, meninges, lymph glands, skin and other tissues of the body. Pulmonary tuberculosis account for over eighty percent of the total cases suffering from

tuberculosis. Transmission occurs by airborne spread of infection droplets and droplet nuclei containing the tubercle bacilli, When a person inhale, those micro particle get lodge in the terminal bronchiole and the alveoli to infect a person.(5) The source of infection is a person with sputum smear positive pulmonary tuberculosis.(6) Each sputum positive case can infect 10-15 individual in a year, if not treated.(7) In recent years, international attention has turned toward the evolving burden of drug resistance. Multi-drug resistant tuberculosis (MDR TB) has emerged in epidemic proportions in the wake of widespread HIV infection in the world's poorest populations, including subSaharan Africa. Extensively drug-resistant TB (XDR TB) was first reported in 2006 but has now been documented on six continents. These trends are critically important for global health, since drug-resistant TB mortality rates are high and second and third-line agents for the treatment of drug-resistant TB are less potent and less tolerable than first-line therapies. Drug resistant tuberculosis (DR-TB) poses a great threat to the eradication of TB. Therefore, preventing the disease is the key to saving lives and resources. Social and behavioral variables play a big part in this prevention. It is important to determine the social factors that may lead to DR-TB in order to set up prevention programs and more efficient treatment regimens. 3 Globally, 5% of TB cases were estimated to have had MDR-TB in 2015 (3.9% of new and 21% of previously treated TB cases).Drug resistance surveillance data show that an estimated 480 000 people developed MDR-TB in 2015 and 210 000 people died. Extensively drugresistant TB (XDR-TB) has been reported by 117 countries in 2015. On average, an estimated 9% of people with MDR-TB have XDR-TB. (8) India has highest burden of both TB and MDR TB and second highest of HIV associated TB based on estimates reported in global TB Report 2015. An estimated 71,000 cases of MDRTB emerge annually from the notified cases of pulmonary TB in India . Based on sub-national DR surveys carried out in three state of India ,- 3% among new TB cases and 12%-17% among previously treated TB cases have MDR-TB.(9) The disease is not only medical problem or a public health problem but is also a critical social problem of great magnitude. Base line and adequate information on epidemiology, past history of anti tubercular drug and pattern of drug resistance is required for its control and effective treatment. Drug resistance in tuberculosis is a global problem and India is no exception to this. However, this rise is mainly among the previously treated cases as previous anti-tuberculosis therapy is the single most important risk factor for the development of drug resistance. The worldwide prevalence of drug resistant tuberculosis is on the rise and multiple studies give varying data regarding the epidemiology of drug resistant tuberculosis. This study was taken up to determine the demographic profile of a patient, previous history of anti tubercular drug intake and pattern of drug resistant

AIMS and OBJECTIVES:

1. To find out the association of Drug resistant TB with demographic, environmental and socio-economic factor.

2. To assess present and past history of anti tubercular drug

3. To determine the pattern of drug resistance in them.

MATERIALS and METHODS:

The present study entitled ” An epidemiological study of drug resistant tuberculosis cases registered under dots plus center in a rural based tertiary care hospital” was undertaken as a mandatory research activity for M.D Tuberculosis and Respiratory Diseases by the researchers as per the Post Graduate research under the Department of Pulmonary Medicine, Burdwan Medical College and Hospital, Burdwan, West Bengal Study Design: This study was a cross-sectional, descriptive. Study Population: Patient who are Sputum positive, diagnosed drug resistant tuberculosis and fulfill the inclusion and exclusion criteria, admitted from March 2015 February 2016 in DOTS PLUS center, Burdwan Medical College and Hospital, Burdwan. Study Area: DOTS PLUS center, Department of Pulmonary medicine, Burdwan Medical College and Hospital, Burdwan.

Gantt Chart : Activities years 2014 2015 2016,(July N o v D e c J a n Fe b Mar Apr May J u n e J u l y A u g S e p O c t N o v D e c J a n F e b Mar A pr May J u n e J u l y A u g S e p O c t) Literature review & topic selection Synopsis writing& submission Questionnaire prep & pre testing Data collection Data entry, analysis& report writing 38

Study period (with Gantt Chart) Total Duration of Study-28 months (July 2014-October 2016) Literature Review and topic selection=5 months Synopsis writing and submission=2 months Questionnaire preparation and pre-testing=2 months Data

collection=12 months Data entry, analysis, report writing and thesis submission=7 months Sample Design: Inclusion Criteria: 1. Patient of age >18 yrs 2. Both sexes 3. Sputum positive patient 4. Patients with proved drug resistant tuberculosis 5. Patient admitted for 7 days in DOTS PLUS center

Exclusion Criteria: 1. Patient refusal

2. Patient of age <18 yrs

3. Patient admitted <7 days in DOTS PLUS center

4. Admitted patient with poor general condition

5. Pregnancy and lactation

SAMPLE SIZE: 106 drug resistant tuberculosis patients.

STUDY DESIGN: An observational cross sectional study.

PARAMETERS TO BE STUDIED:

1. HB%, TC, DC, ESR

2. Blood urea, serum creatinine

3. Liver function test

4. FBS/ PPBS

5. Sputum for AFB stain and gram stain

6. CBNAAT

7. Line probe assay

8. Urine albumin, sugar and microscopy

9. Chest X-RAY PA view

H. STUDY TOOL:

1. Preformed history sheet for treatment history of tuberculosis

2. Sputum microscopy,

3. CBNAAT

4. Line probe assay

5. Chest x-ray,

Ethical clearance Ethical approval for the study was obtained from Ethical Committee of BMCH,

Burdwan. Interview with study subjects were conducted after written informed consent.

Data collection techniques The subjects were explained about the purpose of study. Data was collected by interview method using the pre designed, pre tested questionnaire after taking informed consent from each study subject.

Data entry and analysis Proper template was generated for data entry in MS-Excel. Data entry was done and 10% of data were randomly checked to assure the quality of data entry under the supervision of Guide. The data were analysed by using software-Statistical Package for Social Science (SPSS) 20.0 VERSION. Frequency tables were generated to see the distribution of variable.

• Joint family- It consists of a number of married couples and their children who lives together in the same household and all the property is held in common.(34)

• Nuclear family- It consists of married couple and their children whlie they are still regarded as dependents.

• Overcrowding-It refers to the situation where more people are living within a single dwelling than there is space for, so that the movement is restricted, privacy hampered, hygiene impossible, rest and sleep difficult.(34)

• Criteria for overcrowding- Number of person in the household divided by the number of rooms in the dwelling.

The accepted standard are1 room- 2 person

2 room- 3 person

3 room- 5 person

4 room- 7 room

5 or more rooms- 10 persons (additional 2 for each further room)

Modified Kuppuswamy's Socioeconomic Status Scale classification 2014(82)

Education of the Head Score

1 Profession or Honours 7

2 Graduate or post graduate 6

3 Intermediate or post high school diploma 5

4 High school certificate 4

5 Middle school certificate 3

6 Primary school certificate 2

7 Illiterate

RESULTS and ANALYSIS:

The present study entitled an epidemiological study of drug resistant tuberculosis cases registered under dots plus centre in a rural based tertiary care hospital was carried out in Burdwan Medical Collage and Hospital, Burdwan.

Table 1: Age wise distribution of TB patients (n=100)

Age	Male	%	Female	%	Total	%
18-25	16	16	13	13	29	29
26-35	22	22	02	02	24	24
36-45	17	17	01	01	18	18
46-55	15	15	01	01	16	16
56-65	10	10	01	01	11	11
>65	02	02	00	00	02	02
Total	82	82	18	18	100	100

In our study 29% patient of MDR TB were in the age group 18-25. 24% in age group of

26-35, 18% in age group of 36-45. 16% in age group of 46-55, 11% in age group of 56-65 and only 2% were in the group more than 65 year. The male: female ratio in the MDR group was 4.51:1. The result shows that there is predominance of younger age group. Mean age with SD was 36.6 ± 13.9 with the maximum age being 72 yrs. and minimum of 18 yrs.

Table 2: Sex wise distribution of MDR TB patients (n=100)

Sex	Number	Percentage (%)
Male	82	82
Female	18	18
Total	100	100

Out of 100 patients, majority patients were male (82%) while less than one fourth (18%) were females. This could be due to more exposure of males to outside environment and female often used to ignore their initial symptom due to their responsibilities towards their families as well as children.

Majority (59%) patients were Hindu followed by Muslim (29%) patients. Only some of the patients were belonged to Christian (4%) and other (8%). This finding is almost in accordance with the religion wise distribution of population in the state.

As far as area is concerned majority (65%) patients were belonged to rural area and less number (35%) ware belonged to urban area. This could be due to the fact that 68.13% of people live in the rural area and 31.87% of people live in urban area in the West Bengal state.

Table 3: Distribution of patients on the basis of educational status

Education	Number	Percentage (%)
Profession or Honours	00	00
Graduate or post graduate	08	08
Intermediate or post high school diploma	08	08
High school certificate	22	22
Middle school certificate	19	19
Primary school certificate	12	12
Illiterate	31	31
Total	100	100

In above table, shows that about one third 31% patients were illiterate followed by high school certificate 22%. About 8% were educated up to intermediate or post high school diploma and above Graduate or post graduate, 19% were Middle school certificate and 12 % were Primary school certificate. The level of education is very much important in health seeking behaviour of MDR tuberculosis patients.

Table 4: Occupation wise distribution of MDR TB patients (n=100)

Occupation	Number	Percentage (%)
Govt. service	03	03
Private job	04	04
Farming	18	18
Self employed	10	10
Daily wages	04	04
Labour	19	19
Student	08	08
Unemployed	22	22
Housewife	12	12
Total	**100**	**100.00**

On the basis of occupation majority 22% of patients were unemployed followed by industrial/factory labour 19% and farmer 18%. 12% patients were housewives and 10% were in self employed. Only few patients were student (8%), daily wages and in private job 4% each.3% patient having govt. job.

On the basis of marital status, more than half (65%) were married patients followed by unmarried (30%) patients. 5% patients were widow/widower. This may be attributed to the fact that married people used to

consult health care centre early by their counterparts so as to live a healthy life. Married women reported abandonment, isolation within the household and a lack of proper care from family members, particularly in-laws.

More than one third (78%) of the patients belonged to joint family and rest (22%) were from nuclear family. The reason for this is that still in India, joint family system is more common.

Table 5: Socio economic status of patients (n=100)

Socioeconomic status*	Number	Percentage
Upper	01	01
Upper middle	08	08
Lower middle	31	31
Upper lower	42	42
Lower	18	18
Total	**100**	**100.00**

***Modified Kuppuswamy's Socioeconomic Status Scale classification 2014**

Out of 100, 42% patients belonged to upper lower class followed by lower middle class 31%. About 18% belongs to lower class. Very few patients belonged to upper class 1% and upper middle class 8%. Majority of the tuberculosis patients belonged to lower SES (upper lower & lower). Very few patients belonged to upper SES (upper class & upper middle class). It reveals that patients from low SES get easily infection from outside environment due to poverty and under nutrition.

Depending on the type of house, majority 37% patients were living in kuccha house followed by patients living in pakka house 36%. Only 26% patients were living in semipakka house. Kachha and semipakka house denotes lower socioeconomic status of the family which led to under nutrition, poverty. These factor's indirectly responsible for occurrence of the tuberculosis.

As overcrowding is important risk factor for tuberculosis. It was also concluded from present study that overcrowding is present in about 66% of the study population. In crowded house a greater degree of shared air space increases exposure to M. tuberculosis. Which can even be more increase by limited air movement in closed space-so a greater risk of infection.

Crowding also has been reported to increase the risk of tuberculosis.

Smoking has direct relation with the progression of the disease of tuberculosis. In the present study more than one third 36% of the patients were present smoker followed by past smoker (17%).There were 47% patients were non smoker.

Table 6: Distribution of patients on the basis of alcohol consumption (n=100)

Alcohol consumption	Number	Percentage (%)
Yes	22	22
No	78	78
Total	**100**	**100.00**

From the above table, only 22% of the patients were alcoholics.

Table 7: Status of past history of TB (n=100)

Past history of TB	Number	Percentage (%)
Present	96	96
Absent	4	4
Total	**100**	**100.00**

In above table shows past history of TB was present in majority of cases 96% cases. Only 4% patients were not having past history of TB. In only few 21% patients, family/neighbour/work place history of past/present TB present, which is also an important risk factor for tuberculosis. This may be due to the fact that patients hide their family status of tuberculosis due to social stigma.

Out of 100 patients, 11% patients were suffering from COPD and asthma, hypertension was found in 6% patients. Immunocompromised state like diabetes were 5%, HIV patients are only 3%. Only 1% case having cardiac diseases.

Table 8: Major symptoms present during admission

Symptoms	Number	Percentage (%)
Cough	74	74
Fever	67	67
Chest pain	20	20
Weight loss	26	26
Haemoptysis	23	23
Shortness of Breath (SOB)	46	46

Most common symptoms is cough (74%) followed by fever (67%), and shortness of breath (46 %), haemoptysis is (23 %).

Table 9: Drug susceptibility pattern (n=100)

Drug	Number Patients	Percentage (%)
Rifampicin	11	11
R+H	77	77
R+H+E	3	3
R+H+S	6	6
R+H+E+S	2	2
R+H+L+A	1	1
Total no of patient	**100**	**100.00**

The number of patients in the table above indicates resistance to the particular drug/drugs only. There were a total of 11 patients with mono resistance to Rifampicin and. However there were 77 patients who were resistant to R+H , 6 patients with resistant to H+R+S, 3 patients resistant to H+R+E and 1 patients with resistant to R+H+S+L(XDR).

Majority of Drug-resistant TB developed in Relapse cases (46%), treatment after defaulter were develop DR-TB is 35%. Only 19% patients belong to treatment after failure in our study.

DISCUSSION:

This study was taken up to determine the prevalence and the clinical profile of Drug Resistant TB cases in the patients coming to Burdwan medical college. In this study, the patients were analyzed based on their age, gender, presenting socioeconomic status, habits, past treatment history, the clinical symptoms at presentation and the drug susceptibility. Age Analysis of the 100 culture-confirmed TB cases showed that Drug resistant was more frequent among patients aged 18 to 45 years (71%). Bhatt Get al Found (83.7%) MDR-TB was more frequent among patients aged 16 to 45 years. In this study the mean age of MDR TB patients was 33.64 ± 11.03 years. whereas in our study it was 35.58±13.6 (18-72). The mean age group and the minimum and maximum age limits were found to be higher in our study population. Gender in our study of 100 patients, 82 were male and 18 were female. The male: female ratio is 4.51:1. In the study by Sharma et al the male to female ratio of the MDR TB patients in a cat II pts. was 3.4:1.However in another study done by Dholakia N male to female ratio was 1:1.Hence there is a lot of variability but a slight male preponderance is obvious taking into the account the various studies including ours. Religion in a study conducted by Bhatt G et al in Ahmadabad found that 76.1% patients were Hindu. 4.9% Muslim. In our study majority (59%) patients were Hindu followed by Muslim (29%) patients. Only some of the patients were belonged to others (8%) and Christian (4%). This finding is almost in accordance with the religion wise distribution of population in the state. Area wise distribution of patients most of the Drug resistant tuberculosis patients are resides in rural (65%) area, 35% patients are resides in urban area. In West Bengal most population come from rural area, about 65. 68 %. 13% population resides in rural area, so data may varies in various studies. Xiao-chun He at al found 70.8% people resides in rural area. Occupation wise distribution Labour (19%) and Farmers (18%) were more vulnerable for drug resistant TB. Tuberculosis is a chronic disease so most of the patients were unemployed (22%). Marahatta SB at al found most of the drug resistant patients were self employed (30%), Himansh Karmkar et al found farmers (21.3%) were more with drug resistant TB. Distribution of patients on basis of marital status Drug resistant were found in 65% married patient in our study. This may be attributed to the fact that married people used to consult health care centre early by their counterparts so as to live a healthy life. Married women reported abandonment, isolation within the household and a lack of proper care from family members, particularly in-laws. Bhatt G et al found in their study that 67.9% were married. Distribution of DR-TB patients on basis of type of family and environment 78% of the patients belonged to joint family and rest 22% were from nuclear family. The reason for this is that still in India, joint family system is more common in India. Depending on the type of house, majority 37% patients were living in kaccha house followed by patients living in pakka house 36%. Only 26% patients were living in semipakka house. Kachha and semipakka house denotes lower socioeconomic status of the family which led to under nutrition, poverty. These factors indirectly responsible for occurrence of the tuberculosis. 66% were lives in overcrowded area in our study, Bhatt G et al found overcrowding only in 47% patients. Regarding socio-economic factors, majority of Drug resistant TB patients were from low socioeconomic status, 42% patients belonged to upper lower class followed by lower middle 31%. About 18% belongs to lower class. It reveals that patients from low SES get easily reinfection from outside environment due to poverty and undernutrition. Bhatt G et al majority of patients belongs to upper lower class (VI) of Modified Prasad's and Kuppuswamy's Classification. Habits Smoking is known risk factors for tuberculosis and studies have

shown that there is about two-times increased risk of infection, progression to tuberculosis and death. Similarly alcohol consumption increases to about three-times the risk of disease associated with consumption >40 g per day. In our study more than one third 36% of the patients were present smoker, only 22% of the patients were alcoholics. Previous treatment history improper treatment in the past, poor patient compliance due to various factors and poor prescribing practices remain the most important risk factors for acquired drug resistance. In our study, among 100 Drug resistant TB pts. 46% were relapse, 35% were defaulters and 19% were failure. In the study done by Bhatt G et al found default in 30.9%, followed by relapse in (28.4%), failure in 22% cases. Clinical features the following symptoms were seen in the patients of the study group - Fever, Cough with or without Expectoration, Breathlessness, Chest Pain, Haemoptysis, and Weight Loss. Most common symptom is cough with or without expectoration is present in 74 patients, followed by fever present in 67 patients, shortness of breath present in 46 patients, 23 and 26 patients having hemoptysis and weight loss, 20 patient had also complaint chest pain. Bhatt G et al found 97.5% patients presented with cough with expectoration was the most common symptom, Other symptoms were fever (95.1%), anorexia and weight loss in (91.4%), breathlessness (38.3%), hemoptysis (23.5%) and chest pain (22.2%). In our study, 11 patients with mono resistance to Rifampicin, 77 patients resistant to R+H , 6 patients with resistant to H+R+S, 3 patients resistant to H+R+E and 1 patients with resistant to R+H+L+A(XDR).

Mono resistance to Streptomycin and Isoniazid was not detected in our study. Sharma et al found 36 patient were MDR, 3 patient were resistant to Rifampicin and 4 patient resistant to H+R+S in their study. (73) Various studies indicate varying data regarding the drug resistance pattern in India. Therefore a large scale nationwide study is required which will give the true picture of the magnitude of this drug resistance menace and also help the authorities in policy making and implementation of area specific programs.

Conclusion

- Most (87%) of the TB patients belonged to productive age group (18-55yrs). This may be attributed to the fact that productive age group people are the breed earners for their family.
- When it comes to gender of the MTB TB patients, majority were males (82%) while more than one-fourth (18%) of the patients were females. This could be due to more exposure of males to working environment, which gives higher chances to come in contact with infectious TB patients.
- As far as religions wise distribution of MTB TB patients were concerned, more than half (59%) of the patients were Hindu followed by (29%) patients, belongs to Muslim.
- Majority (65%) of the TB patients belonged to rural background and (35%) of the patient were from urban area. In rural area, there is lack of qualified health care professionals and lesser availability of health services.
- As far as literacy status of the study population was concerned, majority (31%) of the patient had illiterate and lower education up to Middle school respectively. This finding reflect that people with lower literacy status were most vulnerable group.
- On the basis of occupations, self employed person (22%) followed by industrial/factory labours 19% and farmer 18%. 12% patients were housewives. Only few patients were student (8%), daily wages and in private job 4% each. 3% patient having govt. job. This reveals that farmers and labours were more vulnerable for getting infection with Tuberculosis
- Depending upon the marital status of study population, married patients were TB patients in majority (65%) of the cases.
- On the basis of type of family, over two third (78%) of the patient belonged to joint family and rest (22%) were from nuclear family. It may be due to the fact that still in India, joint family system is more common.
- Out of 100 MDR TB patients, majority (42%) of the MDR TB patients belonged to Upper lower SES. As lower SES are most vulnerable group to be infected with tuberculosis infection due to poverty, ignorance and lack of health care services.
- Depending on the type of house, approximately half (37%) of the patients were residing in kaccha house followed by pakka house (36%). 27% residing in semipakka house.
- As overcrowding is important established risk factor tuberculosis. It was also evident from the

present study that overcrowding was present in most (66%) of the cases.

- In only few (21%) of the study population, family history of recent TB was present. This may be attributed to the fact that patients hide their family status of TB due to social stigma.

- In the present study, (36%) of the patients were present smoker and (17%) cases were past smokers. Non-smoker was TB patients in most of the (47%) cases. This indicates that attention should also be given to non-smoker as they are becoming cough symptomatic in most of the cases.

- Only 22% of the patient were alcoholics

- Out of the 100 TB patients, with chronic illness, COPD and other lung disease was present in 11% of the patient and hypertension was found in 6% of the patients. Diabetes 5% and 3% patent have Diabetes and HIV respectively. Presences of such chronic diseases suppress the immunity and increase the chances of their infection diseases like TB.

- Previous treatment history in our study 46% were relapse, 35% were defaulters and 19% were failure.

- There were a total of 11 patients with mono resistance to Rifampicin. 77 patients who were resistant to R+H , 6 patients with resistant to R+ H+S, 3 patients resistant to R+ H+E and 2 patients with resistant to R+ H+E+S. 1 patient resistant with R+H+L+A(XDR).

- Taking into consideration the resistance at least to H+R (as per the WHO definition for MDR), the total no. of MDR TB patients in this study was found to be 88.

Limitations of the study were

Hospital based study- so the study was limited to the patients admitted to the hospital only.

Duration of the study was only one year.

Number of study subjects were only hundred and six.

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