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Assessment of Risk Factors and Co-Morbidities in Patients Affected with Pulmonary Tuberculosis: A Prospective Hospital Based Observational Study

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INTRODUCTION:

Tuberculosis (TB) is an infectious disease caused by the bacillus Mycobacterium tuberculosis, it typically affects lungs (pulmonary TB) but can affect other sites as well (extra pulmonary TB).[1] Tuberculosis (TB) is a major global health problem causing ill-health among millions of people each year and ranks alongside the human immunodeficiency virus (HIV) as a leading cause of death worldwide resulting in increased morbidity and mortality[1, 5]. Tuberculosis is today the biggest infectious killer among young people and adults. Besides the disease burden, tuberculosis also causes an enormous socio-economic burden to India. DOTS have certainly put a dent to the problem of tuberculosis but still the desired results are not achieved. The present study is an at-tempt to know about the socio-demographic factors affecting the treatment outcome in patients of tuberculosis[16]. Despite successful treatment, a significant permanent damage of lung function has been reported in more than 50% of pulmonary tuberculosis patients[10]. Mycobacterium tuberculosis became 2 of the most common etiologic agent of opportunistic infection associated with the acquired immunodeficiency syndrome; respiratory opportunistic infections caused by these organisms are still major cause of morbidity and mortality among those infected with HIV[11]. With early and timely diagnosis and correct treatment of TB is not only reduces the morbidity and mortality but almost all people with TB can be cured.[1,6] TB is the most frequent major opportunistic infection in HIV infected patients and is the leading cause of mortality among HIV infected patients [4]. Treatment of TB-HIV co-infection is a great challenge, more so in developing countries where TB is the commonest opportunistic infection in HIV infected patients. While resources are limited. Although DOTS program in India has achieved more than targeted 85% cure rate in NSP patients[14].

World scenario:

One third of world population is currently infected with tuberculosis and 1.8 million new cases of tuberculosis arise annually in India alone[12]. The WHO has estimated that about 8 million people worldwide are infected with mycobacterium tuberculosis and each year 1.87 million people die of tuberculosis.[9] Over 1.3 million deaths (including 320,000 HIV infected people) has been caused by TB and three quarters of deaths occurred in Africa, and southeast Asia.[2]TB corresponds to 25% of the total number of avoidable deaths in adults of age between 20-49 years in economically active population in developing countries. It is estimated that about 40%

of Indian population is infected with TB bacteria. The vast majority of who have latent rather than active TB.[8]According to the 2014 WHO Global Tuberculosis Report, Nigeria ranks the highest TB burdened country in Africa with South Africa emerging second. More worrisome is the grim predicted burden of over four million cases of tuberculosis of which one million HIV/TB co-infection are anticipated, between 2015 and 2020.[13]

Indian scenario:

India is the country with the highest burden of TB. According to the WHO statistics for 2014, the estimated incidence of TB for India is 2.2 million cases out of global incidence of 9 million[8].India accounts for the fifth of the global burden of Tuberculosis (TB). The national Annual Risk of Tuberculosis Infection is 1.5% [1] and the prevalence of TB as per the recent estimate by **WHO is 2.186 million[2, 3]. WHO estimated TB mortality in India as 2, 76,000 (24/100,000** population) in 2008[17].

In the 1960, India initiated a National Tuberculosis Programmed (NTP) to combat TB. Expert reviews undertaken by Indian government indicated that less than 30% of patients enrolled completed to the treatment. Major reasons identified for poor completion rates incorporated WHO recommended Directly Observed Treatment Short course (DOTS) global strategy and was known as the "Revised National Tuberculosis[20].

Risk factors associated with Mycobacterium tuberculosis infection is Poverty, stress, poor housing, Poor ventilation, Malnutrition, Alcohol & Air pollution (Cigarette smoke)[3]. Co-Morbidities associated with pulmonary tuberculosis is Communicable diseases & Non Communicable diseases. Communicable diseases like HIV-AIDS & Bacterial, viral, fungal pneumonia. Non Communicable diseases like Diabetes Mellitus & Hyper tension, Chronic lung, kidney diseases, Asthma, Bronchitis, Rheumatoid arthritis[3] etc.

METHODOLOGY:

1) STUDY DESIGN:

The present study is a Prospective, Hospital based observational study and should be carried out on patients admitted and diagnosed with Pulmonary Tuberculosis.

2) STUDY DURATION:

The present study is a prospective, observational hospital based study and was be carried out for a period of six (6) months.

3) STUDY SITE:

NAME: Government Chest and Communicable Disease hospital

ADDRESS: Gov. Chest and Communicable disease hospital, Pedda Walter, Visakhapatnam, Pin Code: 530003, Contact no: 9849903069.

4) STUDY OBJECTIVE:

a) Major Objective:

Identification and assessment of risk factors and co morbidities associated with pulmonary tuberculosis in patients infected with Mycobacterium tuberculosis.

b) Minor Objectives:

To identify the predominant risk factors responsible for pulmonary tubercular infection (e.g. socio economic factors).

To identify the co-morbidities associated with patients infected with pulmonary tuberculosis (e.g. Communicable and non-communicable diseases).

5) STUDY CRITERIA:

Inclusion criteria:

- Patients of either sex, diagnosed to be infected with Mycobacterium tuberculosis satisfying all the Inclusion Criteria was being included into the study.
- Patient of age >12years were be included into the study.
- Patients who are voluntarily willing to give the Informed Consent to participate in the study should be enrolled.

Exclusion criteria:

- Patients who are infected species other than Mycobacterium tuberculosis were excluded.
- Children of age < 12 years and Pregnant women/Tendency to get pregnant were excluded.
- Patients who are not willing to give Informed consent.

6) DATA COLLECTION:

The data for our present study was collected or obtained from various sources like patient's medical records, by reviewing medical history & counseling of patients and their caretakers. Individual data collected was recorded in a suitable well designed DCF (Data Collection Form) and was documented.

INSTITUTIONAL HUMAN ETHICS COMMITTEE (IHEC) APPROVAL:

Institutional Human Ethics committee (IHEC) of King George Hospital (KGH) approval was obtained prior to the initiation of the study.

7) TERMINATION OF THE STUDY:

The Principal Investigator reserves the right to terminate the study for safety reasons of the subjects (if any). Reasons for the termination will be provided to the subjects. The Institutional Review Board (IRB)

may terminate the study if there are any major violations of ethical considerations.

8) WITHDRAWL OF SUBJECTS:

The investigator may withdraw a subject from the study for any of the following reasons:

- ✓ The subject suffers from significant inter-current illness or Undergoes surgery during the course of the study.
- ✓ Any subject found to have entered the study in violation of this protocol. This includes subject meeting any one of the exclusion criteria or if he/she does not meet any one of the Inclusion criteria or if the subject is uncooperative during the study.
- ✓ Any subject who requires the use of an unacceptable concomitant medication
- ✓ If it is felt by the Principal Investigator/Clinical Investigators opinion that it is not in the subject's best interest to continue.
- ✓ Any subject who wants to withdraw his consent at any given point of time of the study.

The details of the withdrawals of the subjects i.e. Date of withdrawal of the subject, reason for the withdrawal etc. will be recorded in a well-designed Data collection form (DCF) and other study documents.

RESULTS AND DISCUSSION:

A total of 202 patients who met the study criteria were enrolled into the study, of which 151 (74.75%) patients were males and 51 (25.24%) were females and out of which 130 (64.35%) patients were found to be adherent and 72 (35.64%) patients were found to be non-adherent to the Anti-tubercular therapy given to them. Medication adherence (ATT) based on gender was assessed and we found that, out of 130 adherent patients 95 (73.07%) were males and 35 (26.92%) were female patients.

Percentage adherence was calculated in both male and female patients and we found that out of 51 female's patients 35 (68.62%) were adherent to their ATT and out of 151 male patients 95 (62.91%) were adherent to their ATT, this indicates that female patients had shown a positive attitude towards their disease and are more adherent to their anti-tubercular therapy than male patients. Similarly, in our study we have also assessed the medication adherence of patients of different age groups ranging from the age (in years) 12-80 (the minimum and maximum age of the patients enrolled are 12 and 80 respectively.). We found that most of the patients 93 (46.03%) belonged to the age group 21-40 of which 60 (46.15%) are adherent and 33 (45.83%) are non-adherent to the ATT. (see Table-1)

Percentage medication adherence (ATT) was calculated in all the age groups and we found that maximum percentage adherence (80%) was observed in elderly patients belonging to the age group 61-80 and least percentage adherence (58.83%) was seen in young patients belonging to the age group 12-20, which is an alarming situation for the health agencies at our study site and district (Visakhapatnam) as it indicates that young patient population has shown poor attitude towards their disease and medication adherence (ATT), which may cause relapse of the disease (PTB) leading to the development of drug resistance by the Mycobacterium and thus therefore resulting in Multi-drug Resistant tuberculosis (MDR-TB) which is highly contagious and very difficult to treat. (See Table-2)

Patient demographics based on marital status:

Marital status of the patients infected with pulmonary tuberculosis was assessed in a study and majority of the patients were found to be married 168 (83.16%), unmarried 34 (16. 83%). Married patients were more infected by pulmonary tuberculosis, of which males were more effected by female (SeeTable-3)

Identification and assessment of risk factors for Pulmonary tuberculosis.

As one of the major objective of our study was to be identified and assess the risk factors responsible for Pulmonary TB infection. We have identified and assessed various risk factors are represented in the table-4

The major risk factor for Pulmonary tuberculosis infection was identified to be poor medication adherence of Anti tubercular drugs 72 (35.643%), followed by mal nutrition 59 (29.207%). Patients who has both alcoholism and cigarette smoking as a common risk factor were found to be 58(28.71%). (SeeFigure-1)

Another major objective of our study was assess various Co-Morbidities associated with Pulmonary tuberculosis. These Co-Morbidities were classified into Non communicable diseases and communicable diseases. Out of 202 patients enrolled in our study, 104(51.485%) patients were found to be associated with Co-Morbidities and were classified into non-communicable diseases and communicable diseases, where Non-communicable diseases account for 83 (79.80%) and communicable diseases account for 21 (20.19%). This indicates that majority of the PTB patients are having Non communicable diseases as Co-morbidity when compared to that of communicable diseases.

Of all Co-morbidities (both Non communicable and communicable), most of the patients with PTB were identified to be having COPD (44.57%) as the major co-morbidity followed by others. In patients with only non-communicable diseases as co-morbidity, majority of the patients 37 (44.57%) had COPD as co-morbidity with pulmonary tuberculosis, followed by Diabetes and Hypertension 16 (19.27%) as common co-morbidities. (see Table-5&Figure-2)

Table-1: Gender-wise distribution of ATT adherent and Non-adherent cases

S.no	Gender	Adherent (n=130)	Non-Adherent (N=72)	Total	% Adherence
1	**Male**	**95 (73.07%)**	**56 (77.77%)**	**151 (74.75%)**	62.91%
2	Female	35 (26.92%)	16 (22.22%)	51 (25.24%)	**68.62%**
3	Total	130 (64.35%)	72 (35.64%)	202	

Table -2: Age-wise distribution of ATT adherent and Non-adherent cases

S.no	Age group	Total (N=202)	Adherent (%) (N=130)	Non-adherent (%) (N=72)	%Adherence
1	12-20	17 (8.41%)	10 (7.69%)	7 (9.72%)	58.83%
2	**21-40**	**93 (46.03%)**	60 (46.15%)	33 (45.83%)	64.51%
3	41-60	67 (33.16%)	40 (30.76%)	27 (37.5%)	59.70%
4	**61-80**	25 (12.37%)	20 (15.38%)	5 (6.94%)	**80.00%**

Table-3: patient demographics based on marital status

S.no	Marital status	Male	Female	Total
1	Married	131 (86.75%)	37(72.54%)	168 (83.16%)
2	Un married	20 (13.3%)	14(27.45%)	34 (16.83%)
3	Total	151	51	202

Table-4: Risk factors associated with tuberculosis

s.no	Risk factors	Gender		Total (n=202)%
		Male	Female	
1	Poor medication adherence	56	16	72 (35.64%)
2	Malnutrition	39	20	59 (29.20%)
3	Alcoholism and Smoking	51	7	58 (28.71%)
4	Poor ventilation at home	7	6	13 (6.43%)

Table- 5: Non-communicable and communicable co-morbidities associated with pulmonary tuberculosis

S.no	Non-communicable disease	Total (n=83)	communicable disease	Total (n=21)
1	COPD	37 (44.57%)	HIV-AIDS	19 (90.47%)
2	Type-II Diabetes Mellitus +Hypertension	16 (19.27%)	Pneumonia	02 (9.52%)
3	Asthma	11 (13.25%)		
4	Acute Bronchitis	3 (3.61%)		

Figure-1: Gender-wise distribution and assessment of risk factors associated with pulmonary tuberculosis

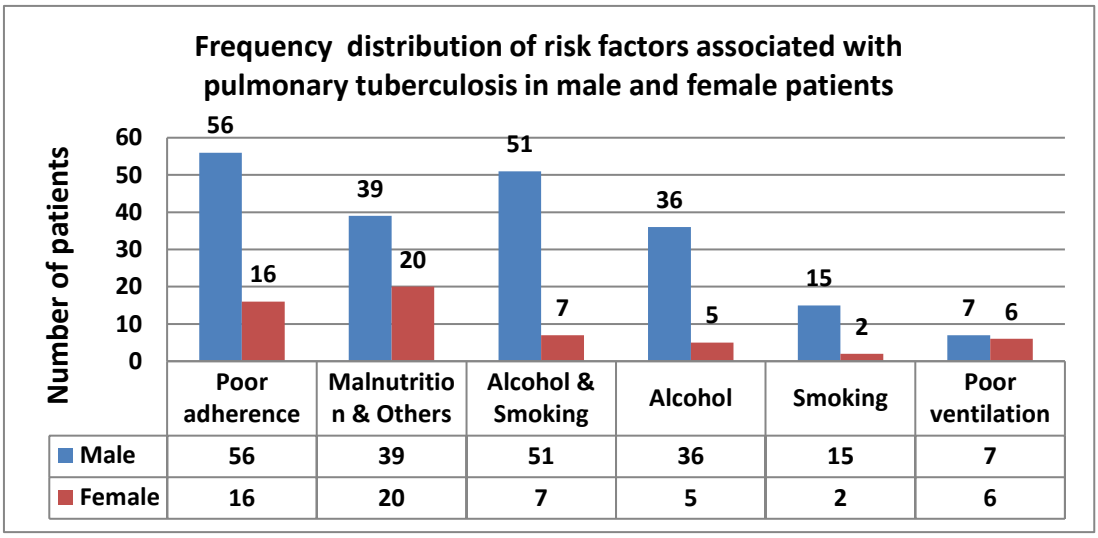
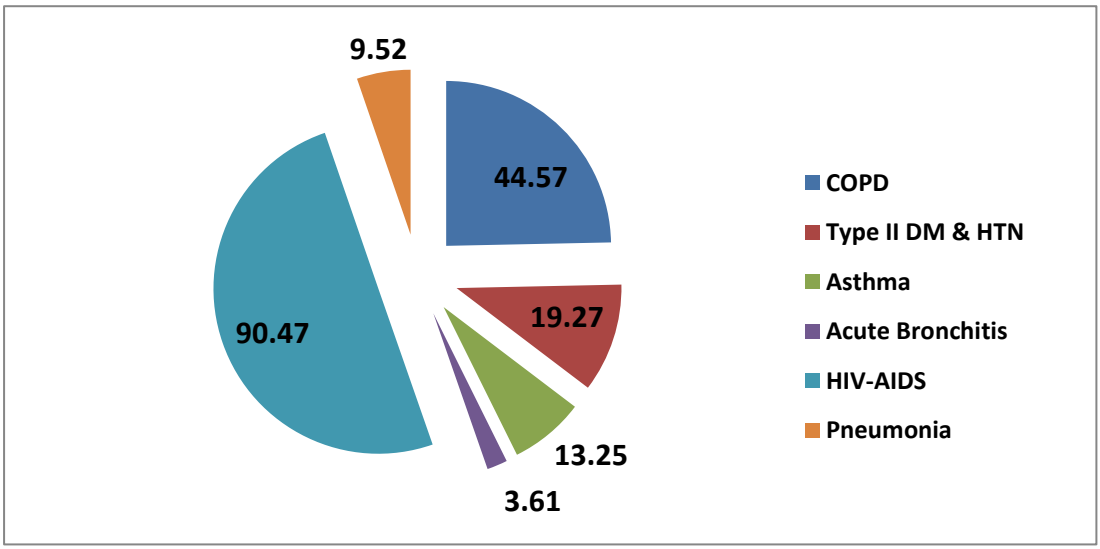


Figure-2: Pie diagram of communicable and non-communicable co-morbidities associated with pulmonary tuberculosis in overall study population



CONCLUSION:

One third of world population is currently infected with tuberculosis and 1.8 million new cases of tuberculosis arise annually in India. It is estimated that about 40% of Indian population is infected with tuberculosis bacteria. WHO recommended Directly Treatment Short course(DOTS) global strategy and was known as the Revised National Tuberculosis, India is the second largest DOTS provider in the world.

Thus is one of the leading causes for morbidity & mortality in patients. The major risk factor for pulmonary tuberculosis was identified to be poor medication adherence, mal nutrition, and alcohol. The major co-morbidities associated with pulmonary tuberculosis were COPD, DM & HTN and HIV, males were more affected more than females.

CONFLICTS OF INTEREST:

There is no financial conflict of interest. This project has not been submitted to any funding agency. This research project is a part of the Post-graduation (M-pharmacy) dissertation work in the area of Pharmaceutical Sciences.

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