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Research Paper

Epidemiology of Tuberculosis and Its Treatment Outcomes: A Prospective Observational Study

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Abstract:
Aim: *The aim of the study was to assess the treatment outcome of TB patients and assess the association of demographic and clinical factors with treatment success of patients.*
Methods: *A prospective observational study was carried out in Guntur, Andhra Pradesh, India for a period of 24months. In this study, we included all patients with culture-positive tuberculosis and extra pulmonary tuberculosis. Patients were categorized based on the sputum culture test. The ADRs were analyzed by using the WHO causality assessment scale. The data was taken on community basis and documented in data collection forms.*
Results: *In the 2-year period from December 2013 to November 2015, 296 cases of tuberculosis were reported, 40 were excluded from study because they are culture negative.When the patients were classified based on the presence of risk factors, TB with the use of alcohols counts more (n=172) followed by TB with tobacco smoking (n=152). Among which pulmonary tuberculosis patients were 84%(n=216) and the remaining were found to have extrapulmonary tuberculosis. Previously treated patients with TB represent 34% of all patients and they were classified in to 4 groups. The patients were treated with both first line and second line drugs, among them 79% (n=203) were treated for drug susceptible TB and 21% (n=53) were identified as resistant to one or more first line drugs so the second line agents were added to the treatment. The most common reason for the treatment failure is non-adherence of patients towards the anti-tubercular therapy. Only 48% (n=122) of patients are found to take complete treatment. Remaining 52%(n=134) discontinued treatment because of many reasons.*
Conclusion:*Multiple factors contributed to the recent increases in the number of TB cases. The effectiveness of TB screening needs further evaluation. Screening of populations at increased risk for tuberculous infection or TB should be expanded.*
Keywords: *Tuberculosis, Extrapulmonary tuberculosis, Treatment outcomes, Non-adherence, Adverse drug reactions.*

I. INTRODUCTION

Tuberculosis (TB) is a major global health problem. It causes ill-health among millions of people each year and ranks alongside the human immunodeficiency virus (HIV) as a leading cause of death worldwide.[7]it is a contagious airborne disease that typically affects the lungs. TB is caused by a bacterium called Mycobacterium tuberculosis. The bacterium can travel through the bloodstream if the TB infection is not treated quickly. It can infect other organs and tissues in the body. Pulmonary TB (PTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree. Miliary TB is classified as PTB because there are lesions in the lungs. Tuberculousintrathoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitutes a case of extrapulmonary TB. A patient with both pulmonary and extrapulmonary TB should be classified as a case of PTB. Extrapulmonary TB (EPTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges.

Risk factors for TB include having a history of:

- HIV/AIDS

- excessive alcohol use
- weakened immune system
- diabetes mellitus

The main goals of tuberculosis treatment are to cure the individual with the disease and minimize the transmission of *Mycobacteriumtuberculosis*to others in the community. Treatment can be challenging for both patients and providers because it requires taking multiple medications for a minimum of 6 months[1]. The consequences of nonadherence to treatment include increased rates of treatment failure, relapse, acquired drug resistance, and prolonged infectiousness of patients.[2,3] Globally, the treatment success rate for people newly diagnosed with TB was 86% in 2013.[7] Even where free medication is available, many patients are not successfully treated for TB.[4,5] Incomplete treatment may result in an extended period of infection, TB resistance to treatment, and lead to increased morbidity and mortality.[6] The aim of the study was to assess the treatment outcome of TB patients and assess the association of demographic and clinical factors with treatment success of patients.

II. METHODS

A prospective observational study was carried out in Guntur, Andhra Pradesh, India for a period of 24months. In this study, we included all patients with culture-positive tuberculosis and extra pulmonary tuberculosis. Patients were categorized based on the sputum culture test. The ADRs were analyzed by using the WHO causality assessment scale. The data was taken on community basis and documented in data collection forms. Data collection forms were reviewed for the following data: dates of treatment, treatment initiation and any changes during treatment, reason for treatment non adherence, age, sex, smear and culture results, presence of pulmonary or extrapulmonary disease, and presence of cavitation on a chest radiograph.

Outcomes: The main outcomes were rates of completion, cure, treatment failed and death. The following outcomes were assessed in all patients.

Acquired drug resistance: Resistance to an antituberculosis drug that occurred during treatment of a patient who had disease that was caused by *M. tuberculosis* initially susceptible to that drug.

Bacteriologic cure:A person who completes all prescribed doses, does not have treatment failure, and is documented to have two or more consecutive negative cultures within 6 months of treatment initiation.

Completion of treatment: Completion of all prescribed doses but lacking bacteriologic proof of cure because of inability to produce sputum.

Cure rate: The sum of bacteriologic cure and completion.

Death due to tuberculosis: Died during the treatment period of tuberculosis after receiving at least 1 week of antituberculosis medications, with tuberculosis as the major contributing cause of death, or died from toxicity due to antituberculosis medications.

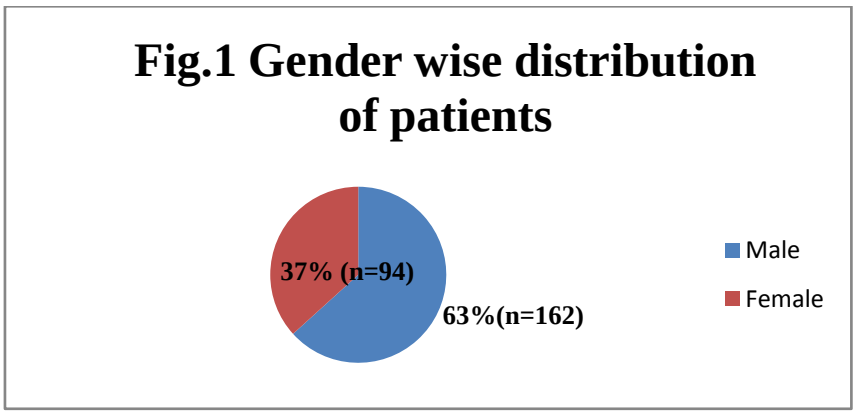
Lost to follow-up: Patients who did not complete therapy because he/she could not be located or patients who do not complete post-treatment evaluation.

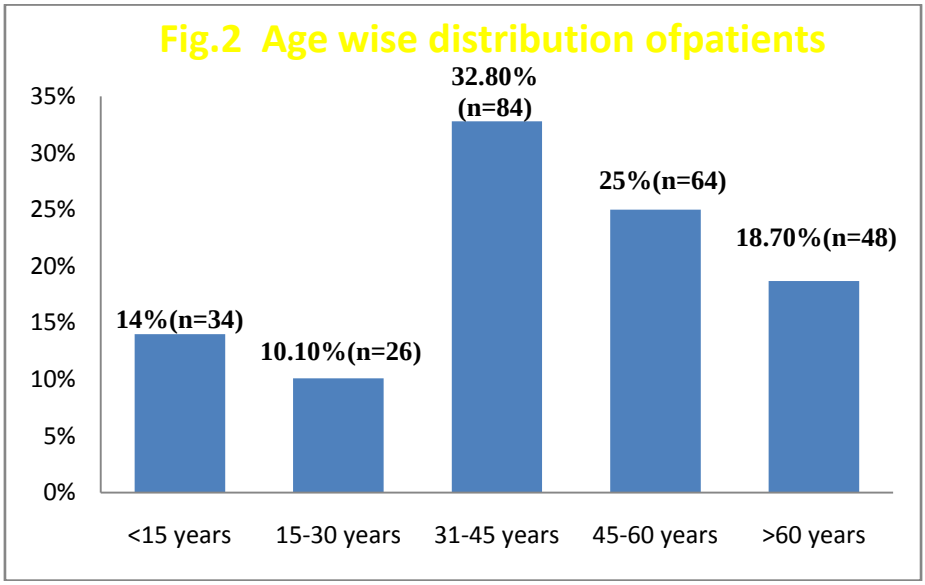
Treatment failure: Presence of a positive culture for *M. tuberculosis* after 4 months of treatment.

III. RESULTS

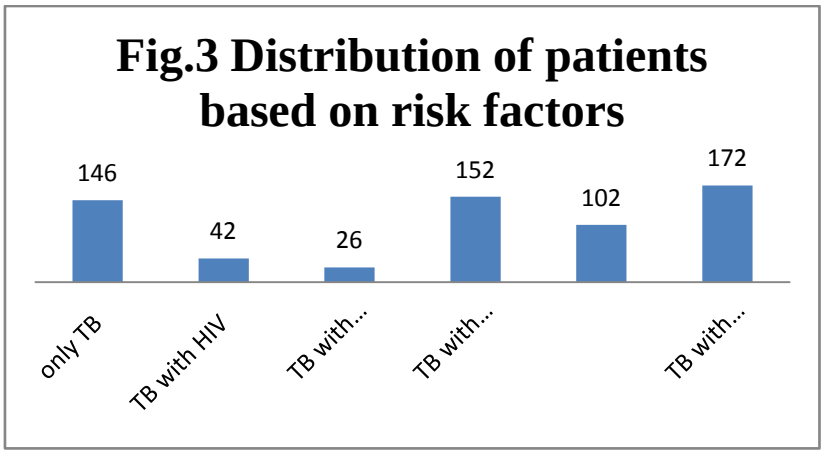
In the 2-year period from December 2013 to November 2015, 296 cases of tuberculosis were reported. Of these, 40 were excluded from the study population because of negative cultures. The remaining 256 patients were included in study population.

Out of 256 patients majority were malei.e. about 63% (n=162) and remaining were female (n=94) [Fig.1].

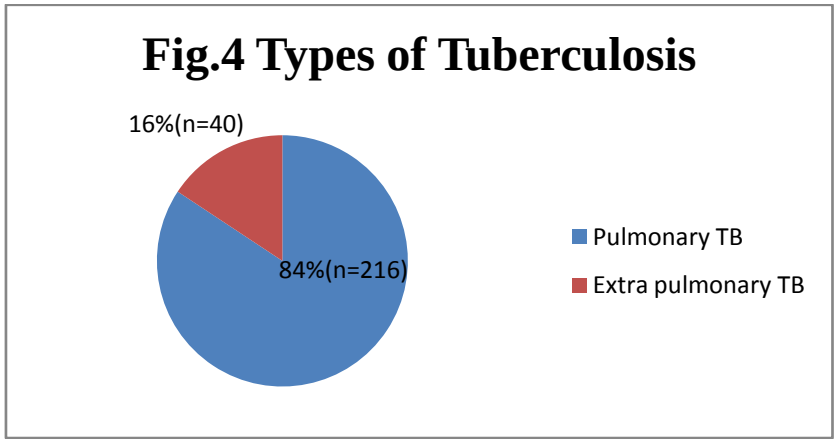




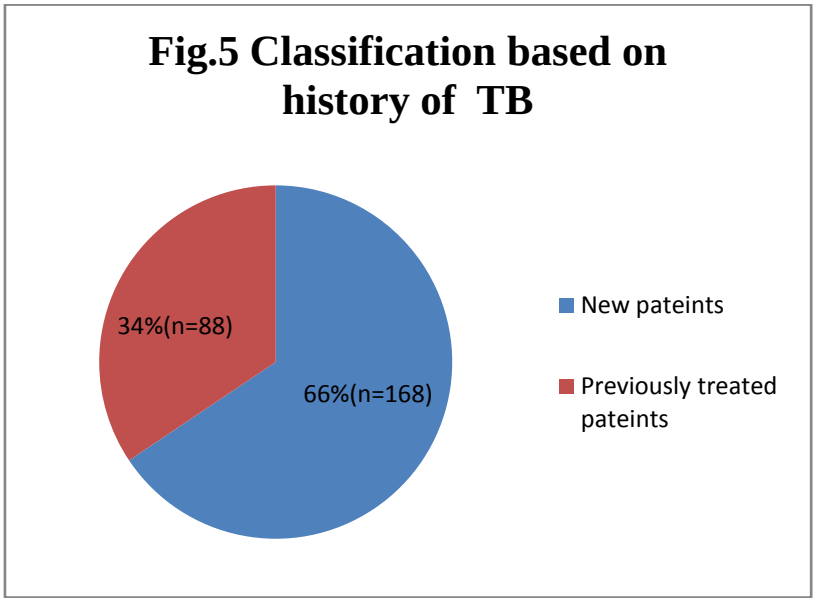
The age wise distribution of patients revealed that most of the patient diagnosed with tuberculosis fall under the age group of 31-45years(32.8%, n=84) followed by the age group 45-60 years(25%, n=64) and age > 60years(18.70%,n=48). Surprisingly the number of pediatric patients exceeded adolescent number. [Fig.2]

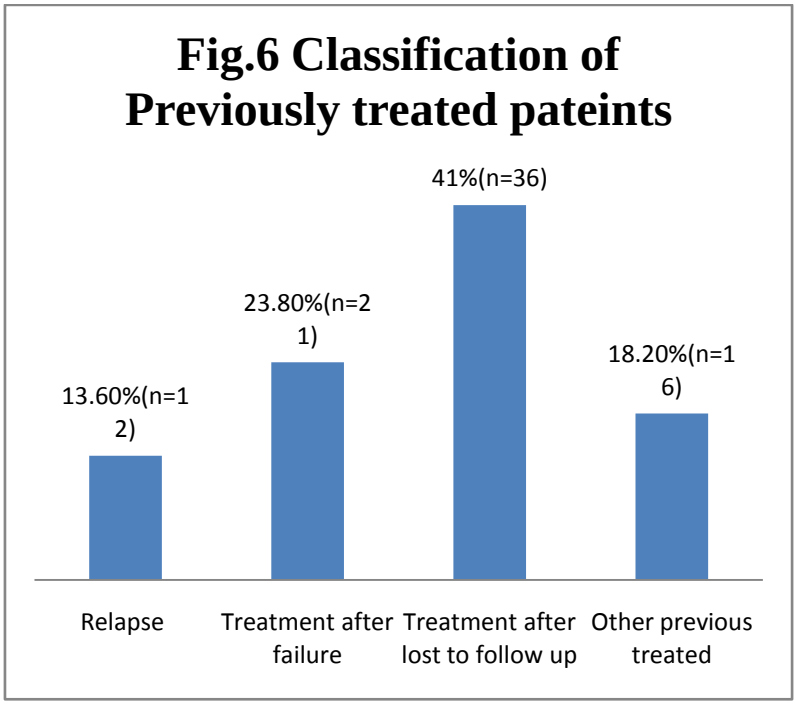


When the patients were classified based on the presence of risk factors, TB with the use of alcohols counts more (n=172) followed by TB with tobacco smoking (n=152). It also reveals that TB is highly associated with malnutrition (n =102). More serious risk factors like diabetes(n=26) and HIV (n= 42) seems to be less but are more fatal. More than half of the patients are not having any risk factors and only presented with TB. Some of the patients are having more than one risk factor.[Fig.3]

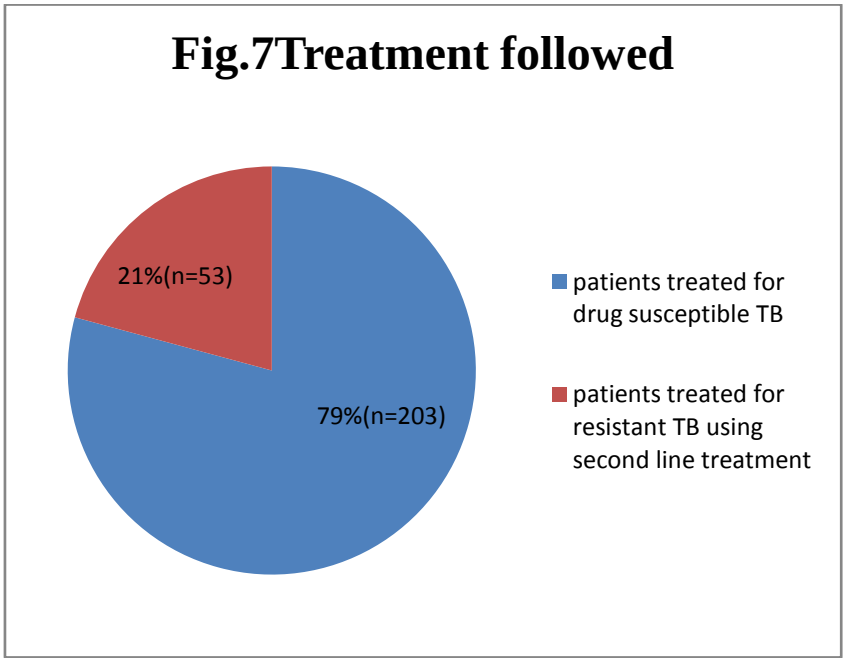


TB Patients were categorized into patients with pulmonary tuberculosis andextrapulmonary tuberculosis. Among which pulmonary tuberculosis patients were 84%(n=216) and the remaining were found to have extrapulmonary tuberculosis.[Fig.4.]. Among 256 patients 66% (n=68) were newly diagnosed with TB and the remaining were previously treated for the disease and stopped treatment without completing regimen because of various reasons. [Fig.5.]

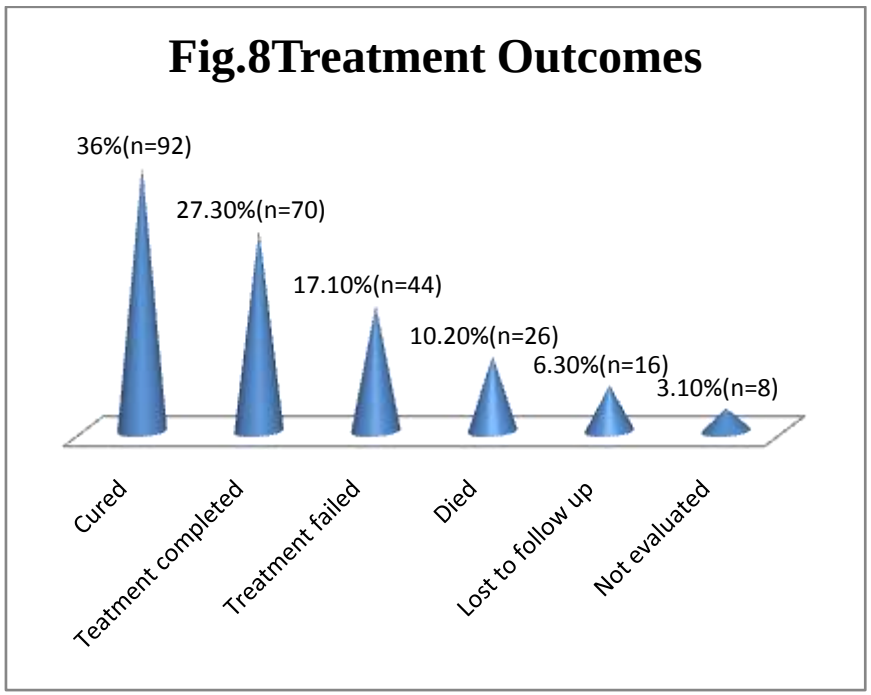




Previously treated patients with TB represent 34% of all patients and they were classified in to 4 groups. Among these many cases were registered for treatment because they lost follow up (n=36, 41%), followed by patients of initial treatment failure (n=21, 23.8%). Some patients registered for the treatment because of disease relapse (n=12, 13.6%) some are not found with any reason but previously treated for the TB.[Fig.6.]

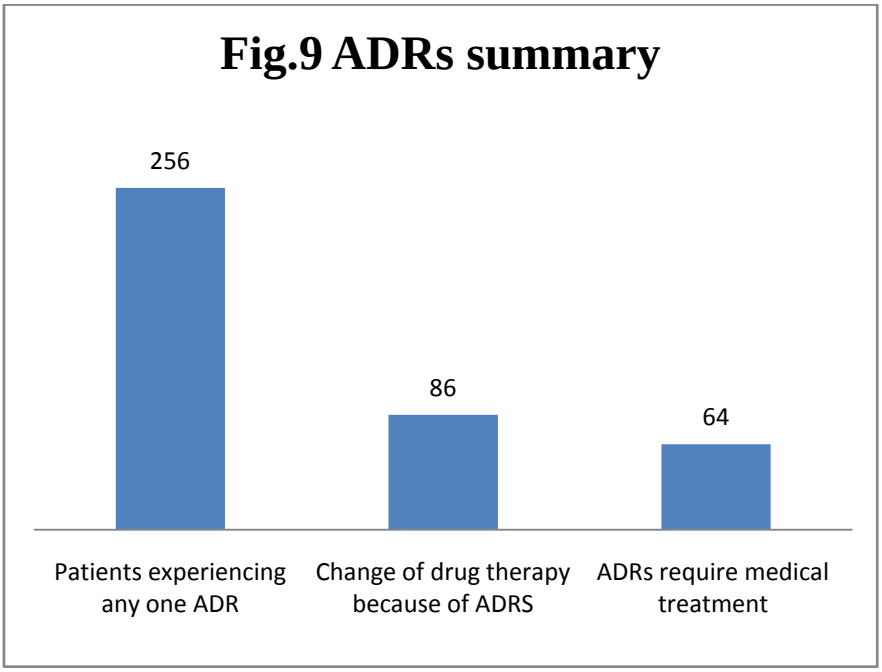


The patients were treated with both first line and second line drugs, among them 79% (n=203) were treated for drug susceptible TB and 21% (n=53) were identified as resistant to one or more first line drugs so the second line agents were added to the treatment.[fig.7]

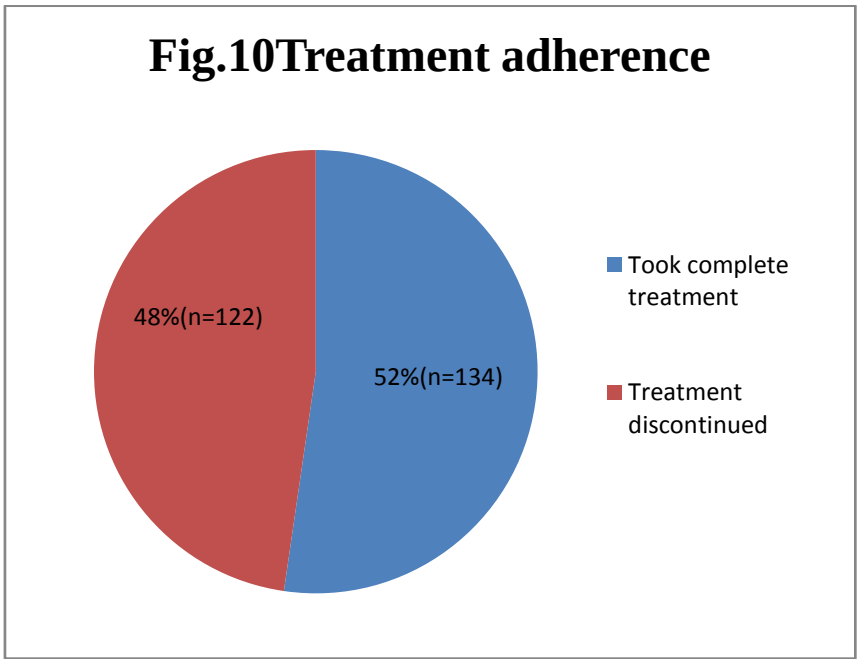


Treatment outcomes among the 256 patients treated by drugs were shown in the Fig.8, which depicts that 36%(n=92) of the patients were completely cured after completion of the therapy. 27.3%(n=70) completed treatment without evidence of failure butwith no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results were unavailable.

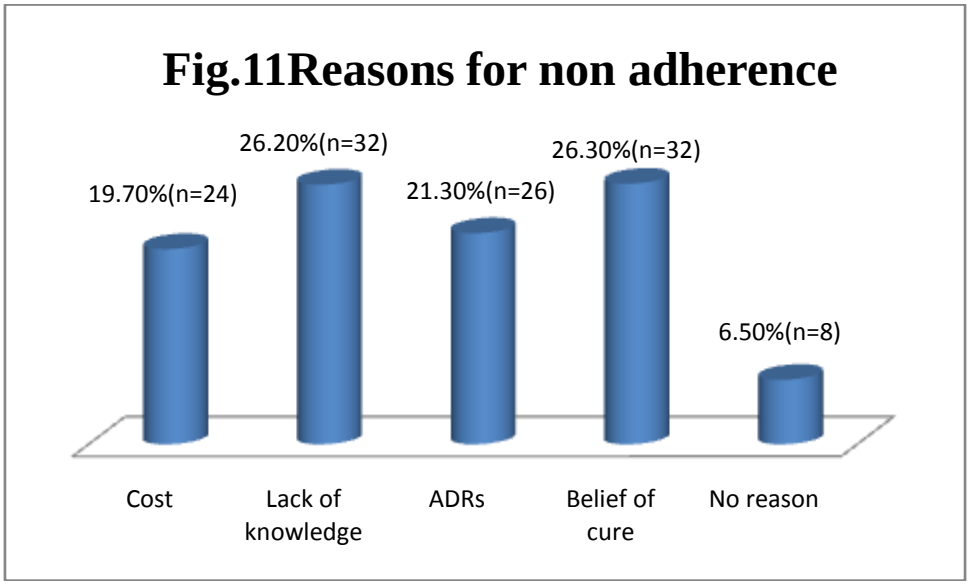
A TB patient whose sputum smear or culture is positive at month 5 or later during treatment were considered as treatment failure patients and they are found to be 17% (n=44). Some of the TB patients (0.2%, n=26) were dead for some reason before starting or during the course of treatment. 16 patients (6.3%) did not start treatment or whose treatment was interrupted for 2 consecutive months or more. A small number of patients (n=8, 3.1%) were not evaluated.[Fig.8]



As the adverse drug reactions are the most common problem in the TB treatment they were detected, analyzed and reported. All the patients who are receiving anti tubercular treatment experienced at least one adverse drug reaction. Some patients need change in drug therapy because of ADRs (n=86). In 64 patients there is a need of medical treatment for the serious adverse drug reactions. [fig.9]



The most common reason for the treatment failure is non-adherence of patients towards the anti-tubercular therapy. Only 48% (n=122) of patients are found to take complete treatment. Remaining 52%(n=134) discontinued treatment because of many reasons. [Fig.10]. There are many reasons for the non-adherence, among them major are lack of knowledge on importance of completing anti-tubercular therapy, which accounts in 21.3% (n=26) and also belief of cure because of symptom relief (26.3%, n=32). ADRs due to drugs is also one of the main reasons for the non-adherence to treatment. As most of the patients belong to low socio economic status cost of treatment is also one of the problem (19.7%,n=24) and 6.5%(n=8) of patients stopped the therapy without any reason. [Fig.11].



IV. Discussion

The total duration of treatment is 6-9 months. Sputum microscopy is done regularly to monitor the response to treatment. Treatment of multi-drug resistant TB is extremely difficult, expensive and often unsuccessful. Once the patient is diagnosed as having TB, the next step is to classify the patient, determine the type of case and the severity of illness to decide the correct combination of drugs and duration of treatment.The male patients are more prone to TB beacause of weakened pulmonary system due to smoking. Patients with all age groups are equally susceptible for the TB. Presence of different risk factors like smoking, alcoholism, diabetes, malnutrition and HIV are the main obstacles for the treatment. A remarkable finding from our study was that most of the patients are non-adherent to treatment, which is the main reason for the treatment failure. Patients without risk factors for non-adherence are having good treatment outcomes. Alcohol, smoking and HIV infection are factors thought to increase tuberculosis mortality. The drug resistance to first line agents is also one of the important factors for the treatment failure and also disease relapse. Early diagnosis and effective treatment of Tuberculosis among HIV-infected patients are critical for controlling the disease. Treatment of active, susceptible tuberculosis with first line drugs is as effective at curing TB in people infected with HIV as in those not infected.

The study has several limitations. The sample size of the study was less, and did not take clustering into account, so we may not have had the power to detect true effects. Caution should be taken when generalizing the results: in general it can be difficult to generalize qualitative results; and the study was restricted to the single place.

The study has a number of strengths. The study allowed the key people involved – those receiving treatment. The community set up can give the more relevant data and found many reasons for the treatment non-adherence.

V. CONCLUSION

Multiple factors contributed to the recent increases in the number of TB cases. The effectiveness of TB screening needs further evaluation. Screening of populations at increased risk for tuberculous infection or TB should be expanded. A number of factors have contributed to the TB crisis, among which, smoking, alcoholism, the emergence of drug-resistant M. tuberculosis strains, confection with HIV socioeconomic decline and deterioration of health care services seem to be most crucial. Provision of counseling and financial support may not only reduce the disease vulnerability, but also increase cure ates.Educationalorcounselinginterventionsmayimprovecompletionoftreatmentfortuberculosis. Early detection and management of ADRs play important role to increase patient adherence and treatment outcomes.

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