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Prevalence of treatment failure among pulmonary tuberculosis patients in a tertiary care teaching hospital

Abstract

Background: Failure of anti tuberculosis treatment can lead to some serious and unwanted consequences. This study aimed to determine the prevalence of treatment failure among patients diagnosed with pulmonary tuberculosis at Mufti Mahmood Memorial Teaching Hospital Dera Ismail Khan Pakistan.

Materials and methods: Consecutive patients of smear positive PTB, managed between February 2011 to October 2013 at the directly observed therapy (Tuberculosis) unit of Mufti Mahmood Memorial Teaching Hospital Dera Ismail Khan Pakistan were enrolled for the study. Each patient was required to have a sputum specimen collected and examined for the presence of acid fast bacilli (AFB). This was done at the time of enrolment into the study and at the end of 2nd (in category I cases only), 3rd (in category II cases only) and at the end 5th and 7thmonth of anti-tuberculosis treatment.

Results: 144 patients were recruited and 20 were lost to follow up or had transferred out. 124 patients consisting of 53 (42.74%) males and 71 (57.26%) females aged 14-85years completed the study. Ninety three (75%) of the patients were New (category I) at the time of enrolment while 31 (25%) were Retreatment cases (category II). Among 124 smear positive patients at baseline, 22 (17.74%) out of 93 were sputum smear positive at the end of 2ndmonth, 2 (2.15%) patients at were sputum smear positive at the end of 5th and 7th month respectively in category-1 patients, and 10 (32.26%) out of 31 patients from category 2 had been sputum positive at the end of 3rdmonth of treatment and 4 (12.90%) patients remained positive at the end of 5th and 7th month of treatment respectively.

Conclusion: Prevalence of treatment failure was significant in our study (4.84%) and it demonstrated a requirement of vigilance on part of health personnel because drug resistant tuberculosis, if untreated, poses a threat to all contacts of patients with tuberculosis.

Keywords: pulmonary tuberculosis, prevalence, treatment failure, drug resistance, MDR, retreatment cases

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Introduction

Infection with *Mycobacterium tuberculosis* or tuberculosis as it is commonly known is present in about one third of the world population.[1] In the year 2009, close to ten million new cases of tuberculosis were reported. The same year tuberculosis was responsible for more than 1million deaths in HIV negative people.[2] Developing countries have the majority of new cases of tuberculosis with close to 85% of new reported cases belonging to these countries.[2] Tuberculosis alone is responsible for more deaths in women of child bearing age than from all-cause maternal mortality.[3] Historically, with the emergence of HIV, a threefold increase in the incidence of various forms of tuberculosis has been noted in countries with a high prevalence of HIV, but more recently a decline in the incidence of tuberculosis was reported in 2009. Tuberculosis is responsible for 25% of deaths in HIV positive patients who have AIDS and in year 2009 alone, tuberculosis killed up to 0.4million HIV positive people across the globe. As compare to HIV negative people, individuals who have concomitant HIV positive disease and *Mycobacterium tuberculosis* infection are 20-30times more apt to have active tuberculosis. The situation is worse when it comes to multiple drug resistant tuberculosis or MDR. In 2009 alone, there were about 0.5million new cases of MDR across the world.[3] 86% of the world's total MDR TB cases are living in 27 countries and Pakistan ranked 4th among these high burden countries.[2]

Similarly, when all cases of tuberculosis across the world are accounted for, 81% of these cases are found in just 22 countries, and sadly, Pakistan is among the top ten countries: at number five.[4] 63% of tuberculosis cases present in the countries that form the eastern mediterranean region is present in Pakistan. According to the World Health Organization, the annual incidence of smear positive cases of tuberculosis is 97 cases per 0.1million population. The annual incidence of new cases of tuberculosis for all types i.e., new tuberculosis, relapse tuberculosis etc. is 231/100,000. In other words about 420,000 new cases of tuberculosis are diagnosed each year. Likewise, Pakistan has a higher prevalence of tuberculosis too: the prevalence of tuberculosis is estimated to be 373 cases per 100,000 population or about 670,000 cases.[5] The overall share of tuberculosis in the total disease burden in Pakistan is 5.1%.

Tuberculosis also exerts a significant bearing on the socio-economic condition of the patients.[6] Smear positivity of a tuberculosis patient should not be taken lightly as the smear positive patients are the most infectious, and are more likely to have a poor out-come in the absence of appropriate treatment. The fatality of tuberculosis can

be judged from the fact that if left untreated, 70% of HIV negative smears positive pulmonary tuberculosis patients will be dead within 10years of diagnosis. The 10-year mortality for HIV-negative, smear negative tuberculosis cases is just 20% for the same period.[7]

There are serious consequences of not completing tuberculosis chemotherapy. These include persisting infectiveness, a serious risk of precipitation of drug resistance. Resistance to anti tuberculosis treatment is usually a multifactorial problem. Many factors contribute to this problem including, irregular supply of anti tuberculosis drugs, poorly structured treatment regimens, poor compliance with treatment either because of lack of education or because of adverse effects of anti tuberculosis drugs. All these factors lead to inadequate treatment of tuberculosis which plays an important role in precipitation of drug resistance. Resistance to anti tuberculosis drugs is one the many threats to the success of tuberculosis-control programs throughout the world.[8]

Materials and methods

This descriptive cross sectional study was carried out at Mufti Mahmood Memorial Teaching Hospital, Dera Ismail Khan Pakistan. The hospital provides services for patients diagnosed with tuberculosis and it is supported by the National Tuberculosis Control Programme Pakistan (NTCP). Laboratory services for sputum microscopy and the drug regimen for the treatment of tuberculosis are in agreement with the protocol provided by the National Tuberculosis Control Programme.

Consecutive non probability sampling was used and patients enrolled were those who had been diagnosed as smear positive cases of pulmonary tuberculosis at the Tuberculosis clinic of the hospital. Before enrolment, the patients were provided information about the consequences of treatment failure and potential predictors of treatment failure e.g., non- or poor-compliance with the treatment of tuberculosis. An informed consent was obtained from the patients. Relevant demographic data was recorded on a pro forma. Patients of age less than 5years were excluded. Patients' sputum samples were collected before treatment for acid fast bacilli (AFB) examination. On the basis of past history of treatment of tuberculosis of any type, these patients were categorized as either new cases (category I) or Retreatment cases (category II). The enrolled patients were followed till completion of treatment. These patients were given 8months of anti-tuberculosis treatment under DOTS. Sputum examinations were repeated at 2nd month (in case of category I only), 3rd month (in case of category II only), 5th month and 7th month of treatment. Data were entered into and analyzed using SPSS version 16.0.

Results

There were 144 study participants. These patients were enrolled into the study between February 2011 and October 2013. Of these 144 patients, 20 patients either transferred out or were lost to follow up. The remaining 124 patients who completed the anti-tuberculosis treatment were evaluated at the end of study. Of these study participants, 93 (75%) were new cases (category I) of pulmonary tuberculosis and 31(25%) were retreatment cases (category II). There were 71 (57.26%) females and 53 (42.74%) males. While the youngest patient was 14years old and the oldest patient was 85years old, the majority of patients (47.58%) were older than 45years with 6 patients above 80years. 22 (23.65%) patients were sputum positive at the end of 2nd month among category 1 patients, while 10 (32.26%) patients in the re-treatment group were found to be sputum positive at the end of 3rd month of treatment. Overall, 6 (4.84%) patients were sputum smear positive at the end of 5th and 7th months respectively. Treatment failure was identified in 6 (4.84%) patients. 4 of these patients belonged to category 2 and the remaining two had been diagnosed with tuberculosis for the first time. These patients had remained sputum smear positive after 7months of treatment with anti-tuberculosis treatment revealing the prevalence of treatment failure in these patients. Drug susceptibility testing was offered to these patients and was possible in three of these patients. Multi drug resistant tuberculosis was diagnosed in all three patients who underwent drug susceptibility testing (Table 1-5).

Table 1 Treatment Categories of study participants (n=124)

Treatment category	No. of participants
Category I	93 (75%)
Category II	31 (25%)

Table 2 Age distribution of study participants (n=124)

Age category (years)	No. of participants	% age
14-May	1	0.8
15-24	30	24.25
25-34	19	15.32
35-44	15	12.1
≥45	59	47.58

Table 3 Patients' types of study participants (n=124)

Patients' type	Frequency	% age
New	93	75
Relapse	8	6.45
Failure	2	1.61
Defaulted	6	4.84
Transferred in	2	1.62%
Other	13	10.48

Table 4 Sputum Smear results during the study period for new cases of tuberculosis (Category 1)

AFB result	At the start of study	At the end of 2nd month	At the end of 5th month	At the end of 7th month
Positive	93 (100%)	22 (23.65%)	2 (2.15%)	2 (2.15%)
Negative	None	71 (76.34%)	91 (97.85%)	91 (97.85%)
Total	93 (100%)	93 (100%)	93 (100%)	93 (100%)

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Table 5 Sputum Smear results during the study period for Retreatment cases of tuberculosis (Category 2)

AFB result	At the start of study	At the end of 2nd month	At the end of 5th month	At the end of 7th month
Positive	31 (100%)	10 (32.26%)	4 (12.90%)	4 (12.90%)
Negative	None	21 (67.74%)	27 (87.10%)	27 (87.10%)
Total	31 (100%)	31 (100%)	31 (100%)	31 (100%)

Discussion

The results of this study showed that tuberculosis had affected mainly the middle-aged and elderly in our environment (47.58% of study participants older than 45years of age). This finding is also observed in some studies from the developed countries,[9] while in developing countries it affects mainly the young age group.[10] One reason may be the changing circumstances in the less developed countries and further large scale studies may highlight the issue. Greater percentage of our study population was females which again is different from studies in our region.[10,11] Treatment failure rate among our patients was 4.84%. 6 patients still had sputum smear positivity at the end of 7th month of treatment and they were declared as treatment failures according to the National Tuberculosis Control Programme guidelines. Though this is lower than reported in many studies we still need to further improve it. On the other hand, there was a considerable difference between the cure rates of tuberculosis in our study from that reported by other studies in the same region. Studies from Bangalore and Tamil Nadu have reported tuberculosis cure rates of 65.7% and 75% respectively.[12,13] The World Health Organization guidelines have recommended achieving cure rate of 85%. Owing to the increased infectiousness, patients with smear positive tuberculosis are more likely to transmit this disease to their contacts which include the hospital staff involved in their treatment, their close relatives and members of general public. They are the focus for infection control measures, and contact investigations. The smear positive tuberculosis patients need to be isolated because of the risk of spreading infection (Figure 1).

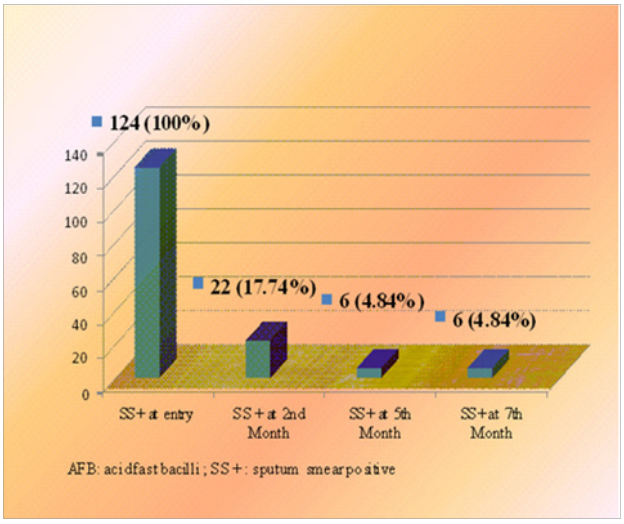

Figure 1 Serial Sputum AFB results of study participants who were smear positive at entry (n=124).

Treatment failure further increases the risk. These are the cases where there are much chances of drug resistance including multidrug resistance and extended drug resistance. Drug resistance is a global health concern and effective programmatic therapy of the smear positive cases is one of the cornerstones in its prevention. Facilities for rapid detection of rifampicin resistance are being made available throughout the country which can help in early detection of drug resistant cases. Physicians involved in TB management need to be involved in its programmatic management and timely referrals for testing resistance in appropriate cases. It is clear from these studies that the use of drug susceptibility testing should become mandatory in the management of all retreatment cases of tuberculosis and in patients with a compatible history and clinical indications of imminent treatment failure.[14]

In addition to multi- and extensive-drug resistance tuberculosis, total drug resistance tuberculosis has also been identified in some patients which is completely resistant to the conventional anti-tuberculosis drugs. Emergence of total drug resistance tuberculosis is a serious threat to the tuberculosis control programs. Drug resistant tuberculosis also brings about additional huge stress of loneliness and branding onto the patients with tuberculosis.[15] Many predictors of treatment failure have been identified in patients with tuberculosis. They include, among others, poor quality of drugs, lack of health education, and presence of co-morbid conditions such as HIV or diabetes mellitus, and non-compliance with anti tuberculosis treatment. Our study aimed to find the prevalence of treatment failure in patients diagnosed with tuberculosis and did not focus on these factors.

According to observations made in many countries, only directly observed therapy is capable of improving treatment outcomes.[16–19] The effectiveness of the DOTS strategy is also confirmed by our own studies. In conclusion, the prevalence of treatment failure in our setup was quite high (4.84%). Early detection of drug resistance in treatment failure patients via sputum culture and drug susceptibility testing can lead to prompt and effective management of these patients resulting in a decreased overall prevalence of tuberculosis.[20]

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None.

Conflict of interest

The author declares no conflict of interest.

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