Original Article

Analysis of factors influencing lack of response in patients under Revised National Tuberculosis Control Programme (RNTCP) protocol

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Tuberculosis (TB) is one of the most prevailing, contagious, chronic and a morbid infection. Our country has a high burden of TB. According to 2015 WHO statistics, India alone accounts to 23% of the total global incidence of TB cases. It is essential to provide complete and proper treatment as it is a contagious disease with high incidence. Though being curable, there is no 100% treatment success rate. If it is not treated properly, it can be fatal. To identify the various underlying factors affecting the treatment failure rate. Once the factors are identified, then the targeted strategies to address them can be formulated. It is a cross sectional study. Recorded cases of patients who were with sputum positive results despite undergoing TB treatment were included. The patients were interviewed using a questionnaire. Data were analysed using MS Excel. Among the retreatment cases most of them were from a low income profile. Most of them were malnourished. Nearly half of them had a positive history of TB in the surroundings. A quarter of them were co infected with HIV. More than half of them were smokers or alcoholic. There was discontinuity of drugs in half of the cases due to various side effects and some discontinued with a feeling of being cured. A few did not use the drugs regularly. Treating the underlying causes is essential to ensure successful treatment. Proper nutrition should be provided along with appropriate health education. There should be proper monitoring of the drug intake and any side effects should be treated immediately to ensure continuous usage.

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Key words **: Tuberculosis, RNTCP, DOTS, TB Retreatment, TB treatment failure reasons, factors affecting treatment.**

Tuberculosis is one of the most prevailing, contagious, chronic and a fatal infection. It is caused by the bacterial species Mycobacterium Tuberculosis.

India is the country with the highest burden of TB. The World Health Organization (WHO) statistics for 2015 gave an estimated incidence figure of 2.2 million cases of TB for India out of a global incidence of 9.6 million which nearly accounts to 23% and about 220,000 people die from the disease in India[1].

As it is a highly infectious disease, it can affect anyone but severity of the disease is more in those with any underlying comorbid conditions, especially in immuno-compromised states like HIV. At least one-third of people living with HIV worldwide in 2015, were infected with TB bacteria. People living with HIV are 20 to 30 times more likely to develop active TB disease than people without HIV. HIV and TB form a lethal combination, each speeding the other's progress.

Most people with TB are cured by a strictly followed, 6-month drug regimen that is provided to patients with support and supervision. Inappropriate or incorrect use of antimicrobial drugs, or use of ineffective formulations of drugs (such as use of single drugs, poor quality medicines or bad storage conditions), and premature treatment interruption can cause drug resistance which is much more difficult to be treated[2]. Multidrug resistant TB (MDR-TB) is a big problem because it is more difficult and costly to cure. MDR-TB must be treated with second-line drugs which are less effective, more expensive, and associated with more serious side effects than first-line treatments. MDR-TB takes at least three times longer to cure, usually 18-24 months and has a higher mortality rate overall than drug-susceptible TB[3].

The various suggested reasons behind failure of treatment may be inappropriate guidelines, poor quality, irregular supply, wrong delivery (dose/combination), drugs unsuitable due to drug resistance, lack of money for treatment and/or transport, actual or presumed side effects, lack of commitment to a long course of drugs[4]. Identifying the factors affecting TB treatment will give insights into the reasons behind lack of response and subsequently low treatment success rates.

Once the factors are identified, then the targeted strategies to address them can be formulated.

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Aims and Objectives

To identify the various underlying factors affecting the treatment failure rate of Tuberculosis under RNTCP protocol.

Proper identification and analysis of the factors will benefit the TB patients since the findings could be used to improve the quality of care resulting in the increased treatment success rates.

Material and Methods

It is a cross sectional study.

Recorded cases of patients in a DMC (Designated Microscopy Centre) of a Tuberculosis Unit (TU) in our district who were diagnosed with sputum positive results despite undergoing TB treatment were included in the study.

Sample size : A total of 46 cases were recorded for retreatment during the period of 1 year (September 2015 to September 2016) in the DMC.

Study Area : Designated Microscopy Centre – Dr.PSIMS and RF under the Tuberculosis unit – Gannavaram.

The DMC TB register was used to obtain the list and details of the patients. The register had records of the registered patient's name, contact number, address and date of starting treatment, HIV status, and classification of diagnosis.

It had a total of 198 TB patients notified during the period, September 2015 to September 2016 of which 46 were retreatment cases.

The patients were interviewed using a structured questionnaire. The data obtained were analyzed using MS Excel.

Observation and Results

The number of cases recorded for retreatment during the study period was 46, which constitutes nearly 23% of the total cases. Among the retreatment cases 91% were pulmonary cases and 9% were extra pulmonary. There was a male predominance of 81%. Most of them belonged to the age group of 21-40 years.

Among the cases 96% were found to be malnourished (It was detected using BMI as an index. Those with BMI value below 18.5 were considered to be malnourished). In this study the highest BMI value was 22.2 and the least was 15.2. Most of those who were malnourished (54%) had their BMI values between 17.0-18.4 (mild malnutrition).

BMI Values	Frequency
≥ 18.5	2
17.0-18.4	24
16.0 - 16.9	14
< 16	6

Among the cases 59% were from the low socioeconomic status (modified Kuppuswamy's socio-economic scale) and 57% of the subjects were educated (one who can read and write in any one language is considered educated). Twenty six percent of the cases were co infected with HIV and 11% of them were diagnosed with multi drug resistant TB. On considering diabetic status only 4% were found to be diabetic. Almost 87% of them had normal liver function tests and 54% of them had a positive history of Tuberculosis in the household or workplace. In the study 74% of cases were smokers and 61% were alcoholic. When discontinuity of drugs was considered, 55% of them did so because of actual or presumed side effects. Around 23% of them discontinued drugs with the sense of wellbeing and 22% of them did so as they were forgetful. There was no lack of supply of drugs in this study.

Factors	Frequency (Percentage)
Total TB Cases Recorded : 198	
Retreatment Cases (sample)	46 (23%)
1. Pulmonary	42 (91%)
2. Extra Pulmonary	4 (9%)
Malnourishment :	44 (96%)
Immunocompromised :	
1. Diabetics	2 (4%)
2. HIV Positive	12 (16%)
Resistance :	
Diagnosed With MDR TB	5 (11%)
Social Habits :	
Alcoholic	28 (61%)
Smokers	34 (74%)
History of TB in Surroundings :	
LFT :	25 (54%)
1. Normal	40 (87%)
2. Abnormal	6 (13%)
Discontinuity of Drugs (Reasons) :	
1. Sense of Well being	12 (23%)
2. Side effects	28 (55%)
3. Forgetfulness	11 (22%)
4. Lack of supply	0 (0%)

Discussion

Among all the TB cases (198) notified during a period of one year (September 2015-September 2016) 152 cases were newly diagnosed and 46 cases were previously treated cases. The retreatment cases in this study were nearly 23% of the total cases, which was nearly equal to a study done in Sikkim (27 %)[5].

This study was set out to identify the factors affecting response to TB treatment in a DMC in Gannavaram of Andhra Pradesh.

Among the retreatment cases, 91% were pulmonary and 9% were extra pulmonary. These values were similar to a study done in a tertiary center in Nigeria[6] (Pulmonary 88% and extrapulmonary 12%).

In this study 81% of the recorded cases were males while only 59% of them were males in the Nigerian study. 26% of them were found to be co infected with HIV while 20% were HIV positive in Nigerian study which had a sample size of 76. Among the HIV positive cases 75% of them were males in this study.

Eleven percent of the total cases were those with Multi Drug Resistant TB in this study. Here 45% of the cases of were in the age group of 21-40 years. There were two peaks in the age distribution of the patients, 21-30 years (30.8%) and >50 years (28.2%) in the Nigerian study.

When the factors affecting the TB treatment were

analysed, it was found that 96% of the recorded cases were found to be malnourished in this study. On comparison with a study done in Namibia[7], 69% of them did not have proper supply of food.

When the socio-economic status was taken into consideration, patients were scored using Kuppuswamy's Socio economic scale. In 59% of them belonged to a low income profile which was similar to a study carried out in South Africa. In a similar study in Indonesia 50% of them were with low income while the other 50% had a good income. The findings of this study are contraindicated with a study in India[8] which did not find employment status and income to be significant factors affecting the TB treatment.

Education regarding TB treatment is highly essential to complete the treatment successfully. When this factor is considered, 57% of them were educated. Only 9% of the recorded cases were illiterate in the Indonesian study. But a similar study done in Afghanistan cited that most of the cases recorded for treatment failure were illiterates which was not the case in this study.

Of all the total cases recorded, 4% of them were found to be diabetic. When the liver function tests were analyzed, 87% of the cases had normal LFT. As TB is a contagious disease, any history of TB in the household or locality or workplace was also considered. About 54% of them showed a positive history.

Around 74% of the recorded cases were smokers (daily and occasional). A daily smoker is someone who smokes any tobacco product at least once a day and an occasional smoker is someone who smokes, but not every day as per WHO. In a study in Morocco, smokers were twice as likely to fail tuberculosis treatment as non-smokers. Among patients with pulmonary tuberculosis in India, smokers were found to have a threefold greater risk of recurrent tuberculosis than non-smokers as per a study in South India[9]. But only 29% are smokers amongst those who failed the treatment in a similar study in Namibia. In 61% of the cases in this study were alcoholic (more than 80 gram alcohol in any form) whereas 57% drank alcohol in the Namibia study. Both the studies almost show a similar result regard to alcohol whereas they showed difference in smoking.

If the drugs were discontinued, various reasons for the discontinuity were analyzed in the study. There was discontinuity in 55% of the cases due any actual or presumed side effects like nausea, vomiting, headache, generalized weakness, arthralgia, skin rash. On comparison 47% of the patients also experienced similar side effects in the Namibia study.

In this study, 23% of the patients discontinued the drugs with a feeling of being cured. Almost same percentage of the patients, nearly 27% discontinued the drugs with a similar reason in a study in Namibia. Forty eight percent of them in Nepal[10] stopped the drugs as they were feeling better which is nearly double that of the result obtained in this study.

It was found that 23% of the patients in this study did not the use the drugs as they were forgetful. As per this study, there was no problem regarding the supply of drugs. They received all the drugs on time. There was a similar result regarding the supply of drugs in many other studies too.

Conclusion

On analyzing the results obtained in this study, malnourishment was found to be one of the major reason affecting TB treatment. Along with the regular supply of the drugs, proper nutrition should also be provided to ensure treatment success. Initiation of income-generating activities to improve food provision for patients on TB treatment is also essential.

Proper education to the patient and family members, regarding the treatment and its side effects is essential as the drug regimen is of longer duration. This could be done by giving proper guidelines and regular monitoring of the patients. Mass awareness programs should be initiated at the local level.

Smoking and alcohol can itself be a reason for poor nutrition and immune suppression. Hence to improve the quality of life, de addiction programs are to be initiated for those patients. Side effects due to drug regime have to be immediately attended and an alternative should be provided to ensure continuity of the treatment. There should also be regular supervision of the intake of drugs even by the family members to overcome the problem of forgetfulness. Complete usage of drugs is highly essential to prevent the emergence of more severe drug resistant forms.

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