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Research Article

A study among pulmonary tuberculosis patients under the treatment of directly observed treatment short course with special reference to liver function in tertiary care hospital

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ABSTRACT

Background: Directly observed treatment short course is the most effective life saving measure among the patients suffering from tuberculosis. Drug induced hepatotoxicity is one of the major side of anti-tuberculosis drugs which causes to withdraw the drugs. The objective of the study was to find out certain variables like age, sex and BMI among the patients with pulmonary tuberculosis and to find out liver function after intake of anituberculosis drugs.
Methods: The patients diagnosed first time with pulmonary tuberculosis by sputum positive attending RNTCP DOTS Cell at tertiary care hospital were selected for this study.95 patients enrolled in this study during six months period and they were followed another six months to find out the status of liver function. BMI was measured, the investigation like serum albumin, liver function (aspartate aminotransferase (AST), alanine aminotransferase (ALT) alkaline phosphatase level test (ALP), serum bilirubin) were assessed at the time of initiation of anti-tuberculosis drugs and 2 weeks, 4 weeks and 24 weeks after the drugs. Chi-square test applied as a statistical tool.
Results: Among study population of 95, 54% were male and 46% were female. Nearly 62% of the patients were in the age group of 18 to 48. Around 57% of the patients were underweight according to BMI. The liver function test was abnormal after drugs in 5.2% of the study population.
Conclusions: This study shows that the tuberculosis affects the productive life of the population. The drugs given under DOTS did not harm majority of the patients that shows it is safe to administer the regime.

Keywords: DOTS, Liver function, Serum albumin

INTRODUCTION

Tuberculosis stands as a world-wide health problem although the aetiological agent was discovered more than a century ago and it is highly curable with chemotherapy and vaccine are also available.[1] If properly treated, tuberculosis is curable in almost all cases. If untreated the disease, may be fatal within five years in more than 50% of cases. India has got the highest number of Tuberculosis cases in the world and it contributes to 20% of all cases of tuberculosis and two third cases of TB in South East Asian region. Every year about 1.8 million develop TB newly. Of these, 0.8 million are new smear positive cases. 2 out of every 5 Indians are infected with TB. Each day about 5000 people contract the disease for the first time.[1] person dies every minute and about 1000 people die every day. Development of effective treatment for tuberculosis was one of the most significant advances during the century. The chemotherapy of tuberculosis is now more rationally based than in the treatment of other infectious diseases. Globally DOTS strategy has been recognized as the best approach to TB control. Today

India's DOTS (Directly Observed Treatment Short Course) programme against TB is recognized as the one of most effective programme. In spite of having an effective chemotherapy regimen there are many factors responsible for failure of chemotherapy like poor patient compliance, drug resistance, insufficient duration or insufficient dose and drug induced hepatitis. Unfortunately almost all the chemotherapeutic agents used in tuberculosis treatment are hepatotoxic in one way or other. Drug induced hepatitis caused by anti-tuberculosis treatment ranges from asymptomatic elevation of hepatic enzymes to fulminate hepatic failure and subsequent death. In the absence of overt jaundice, the degree of subclinical hepatotoxicity has to be determined by monitoring the biochemical changes using the liver function tests (LFT). Even though many studies have shown low incidence of Drug induced hepatitis (DIH), a few of the Indian studies have shown a high incidence of hepatitis due to short course chemotherapeutic regimens. Because of the disparities in the results of these studies, a prospective study was undertaken on to find out real situation.

Objectives

- To find out certain variables like age, sex and BMI among the patients with pulmonary tuberculosis.
- To find out liver function after intake of anituberclusis drugs.

METHODS

Study design

This is a descriptive study conducted on newly sputum positive patients at Tuberculosis Cell Thanjavur Government medical college. A study was conducted for one year during June 2014 to May 2015.

The study participants were selected from the patients who were attending Tuberculosis cell at institution with newly sputum positive. During the period from June 2014 to November 2015 nearly 95 study participations were selected for the study according to inclusion and exclusion criteria. The patients were informed about the study and got consent. Mostly the patients nearby area of the institution were selected for easy follow up. Institutional Ethical Committee clearance was obtained. The phone number of the patients was received and phone of the investigator also given for immediate information of side effect. The variable like age, sex and BMI measured. They were provided category I drugs rifampicin, INH, ethambutol and pyrizinamide .The blood was drawn from the patients for liver function test such as aspartate aminotransferase (AST), aalanine aminotransferase (ALT), alkaline phosphatase (ALP) and serum bilirubin. The serum albumin also tested. The investigation was done before initiation of the drugs, after 2weeks, 4 weeks and 24 weeks of drugs. Five times higher than the normal value of liver function test was considered abnormal or hepatotoxic. Those had abnormal value and side effects they were treated accordingly.

Inclusion criteria

All new sputum positive tuberculosis patients above 18 years of age who have registered in the TB cell of Thanjavur medical college from June 1st 2014 to the end of November 2014 and started on ATT for the first time and they were followed for six months after starting therapy.

Patients coming from within and nearby areas of Thanjavur were selected to minimize the dropouts.

Exclusion criteria

- Patients who either had been on ATT previously or were on ATT at the time of the registration in the TB cell.
- Those patients whose baseline liver enzymes were more than upper limit of normal.
- Patients who were on chronic medication for any other disease.
- Sputum negative cases & extra pulmonary TB.
- Patients suffering from any other diseases like diabetes, Hypertension and cardiac failure.

RESULTS

Among the study population of 95, 56% were male and 44% were female. Nearly 62% were in the age of between 18 and 48 shows that they were in productive life period as shown in Table 1. Around 57% were underweight that shows malnutrition was exiting in most of the study participants as shown in Table 2.

Table 1: Distribution of age among study population.

Age in Years	Frequency	Percentage
18-28	21	22
29-38	16	17
39-48	22	23
49-58	18	19
59-68	13	14
>68	05	05
Total	95	100

Table 2: Distribution of BMI among study participants.

BMI	Frequency	Percentage
<18.5	54	57
18.5-24.9	35	37
25-29.9	06	06
30-39.9	00	00
Total	95	100

The serum albumin was lower than normal in 74% of the patients suffering from pulmonary tuberculosis that

shows combine with BMI and albumin many patients were malnourished nearly, 7% of the participants were suffering from severe disease with cavitation of the lung. During the treatment 10 patients (11%) dropped the treatment in the middle of the course. Among the patients under the chemotherapy 5 patients (5.2%) developed abnormal liver function according to their liver function test .Among the hepatotoxicity nearly 4 (80%) patients have not any symptoms of dysfunction of the liver.

There was no significant statistical difference was made between hepatotoxicity and sex and malnutrition. There was statistical significant between severity of the disease and hepatotoxicity due to drugs as shown in Table 3.

Table 3: Association of severity of disease with hepatotoxicity.

Status of disease	Abnormal LFT	Normal LFT	Total
Severe	04	03	07
No severe	01	87	88
Total	05	90	95

Chi square value= 30; P value= 0.0001

Among 95 participants, 2 were positive for HIV but both did not develop any hepatotoxic manifestation after DOTS regime.

DISCUSSION

The present study has found out that most of (62%) the pulmonary tuberculosis are belong to productive age group (18-48) which interferes their quality of life. A similar finding was pointed out by Aktogu[2] in his study that tuberculosis was more common among persons aged 20-39 years of age. According to present study there was 11% of the patients dropped their treatment or default which is closely similar to 15% default a study conducted by Chhaya Mittal et al.[3] This study has identified that 57% are underweight at the time of diagnosis of tuberculosis which is almost similar to 50% a study conducted by Getnet Yimer et al.[4] Like BMI the serum albumin at the time of diagnosis of tuberculosis in74% of the participants is lower than normal which is supported by Surendra K. Sharma[5] has found hypoalbuminaemia in 48%.The present study has found out that only 5.2% had hepatotoxity which is very similar to 5.3% a study conducted by Teleman.[6] But it is much lower than 16% and 23% studies conducted by Surendra K. Sharma et al[6] and Getnet Yimer et al[5] respectively.

T. Schaberg[7] has found out as 11% of the patients developed hepatotoxicity after administration of anti-tuberculosis drugs in his study. 80% of the patients who suffered hepatotoxicity according to investigation did not have any symptoms. This study has found out the severity of the disease is one of the reason for development hepatotoxicity after anti-tuberculosis drugs but malnutrition or sex of individual do not have any relation to hepatotoxicity according to this study. The patients were given adequate treatment for hepatotoxicity and recovered within 1-4 weeks to normal after discontinued of the drug.

CONCLUSION

The occurrence of pulmonary tuberculosis among young people is very obvious and it is suggested for intensive primary prevention than treatment. The defaulters may be followed and should be completed the treatment. The malnutrition also may be prime focus to prevent disease. The hepatotoxicity occurs in low proportion only and it is recommended to implement DOTS therapy for tuberculosis patients to prevent multidrug resistant.

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