A Study On Defaulter Rates Of Pulmonary Tuberculosis Patients Along With The Risk Of Co-Morbidities Among MDR-TB Patients Availing The Dots Facility In Hapur District.

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ABSTRACT:-

Introduction: Tuberculosis (TB) remains one of the top killers in the developing world. This is especially true in India, where each year approximately two million new cases and 500,000 TB related deaths occur. To combat this overwhelming problem, the Government of India piloted and then expanded a strategy of directly observed treatment short-course (DOTS) under the Revised National Tuberculosis Control Programme (RNTCP). Piloted in 1993 and expanded nationally in 1997, DOTS now covers over 1 billion people, almost entire country. Through the help of DOTS programme, RNTCP has achieved improved cure rates and reduction in unfavorable outcomes. Default is one of the unfavorable outcomes for patients on DOTS]. the default rates are relatively higher in Multidrug resistant tuberculosis. Treatment for MDR-TB uses second-line drugs that are less effective than those used for first-line treatment and which often have significant side-effects. It is also lengthy, complex and expensive. As a result, treatment outcomes for patients with MDR-TB are worse than for drug-sensitive TB, with low success rates and high rates of treatment failure and default. While some analyses of MDR-TB treatment cohorts have reported factors associated with negative outcomes of treatment (death, failure and default).

Aims & Objective: The preesent study was undertaken to carry out the default rates, the co-morbidity profile of MDR-TB patients, and the role of comorbidities in the treatment course of MDR-TB under DOTS regimen among MDR-TB patients availing the DOTS facility

Materials And Methods: The present study was carried out to study the defaulter rates of pulmonary Tuberculosis patients along with the risk of co-morbidities of patients in D.O.T.S. sites of Hapur & S.I.M.S. . For this purpose, a total of 100 MDR-TB patients were enrolled in the study and were prospectively followed up. Patients with pulmonary TB diagnosed 2016-17 were of either sex, aged ≥18 years diagnosed with smear positive pulmonary TB (both newly diagnosed and previously treated patients were included in the study. The statistical analysis was done using SPSS Version 20 statistical analysis software. The values were represetend in number (%) and mean±Sd and χ^2 value.

RESULT: During the period of study, 100 patients of pulmonary tuberculosis were enrolled in the study, out of which 27 (27.0%) defaulted during their treatment while 73 (73.0%) completed their treatment successfully. Rate of default in DOTS treatment by patients of pulmonary tuberculosis was 27.0% in the present set up.Age of patients enrolled ranged between 18 & 76 years and majority were male (77.0%), occupied as labourers (79.0%). Age, Gender and Occupation of defaulter and non-defaulter patients were comparable.Most common reason of default was Intolerance of treatment (92.59%), followed by hepatic insufficiency (66.67%), Renal insufficiency (29.63%) and Diabetes (7.41%).

CONCLUSION: The findings of present study provided useful information regarding the demographic and clinical profile of MDR-tuberculosis patients and their default rate for DOTS treatment. The findings of study showed that in a low resource setting primarily catering to lower socioeconomic strata the default rate is moderately high, and in most of the cases adverse drug reactions were the reason for default. Hence, it is recommended that patients be properly counseled regarding the possible side effects of the drug and their remedies. Moreover, comprehensive health care provision should be integrated in DOTS programme to ensure an absolute compliance and to tackle different side effects associated with DOTS therapy in MDR tuberculosis patients.

Keywords:- *pulmonary tuberculosis,MDR-TB,co-morbidities*

I. INTRODUCTION

Tuberculosis causes ill-health for approximately 10 million people each year and is one of the top ten causes of death worldwide. For the past 5 years, it has been the leading cause of death from a single infectious

agent, ranking above HIV/AIDS. This is despite the fact that, with a timely diagnosis and correct treatment, most people who develop TB disease can be cured. World Health Organization (WHO) aimed to dramatically reduce the global burden of tuberculosis by 2015 by ensuring that all TB patients benefit from universal access to high-quality diagnosis and patient-centered treatment. However, this seems to be a far reaching goal considering the fact that the deadlines fixed for eradication of tuberculosis and proposals in its marked reduction over the years have remained surpassed several times during the last few decades. Mycobacterium tuberculosis H37Rv (M. tuberculosis H37Rv) is the causative agent of tuberculosis. Resurgence in Tuberculosis cases has been recorded all over the world with about 8 million people estimated of being infected with the disease. Tuberculosis remains an endemic and is the seventh leading cause of death globally. Tuberculosis (TB) remains one of the top killers in the developing world. This is especially true in India, where each year approximately two million new cases and 500,000 TB related deaths occur. To combat this overwhelming problem, the Government of India piloted and then expanded a strategy of directly observed treatment short-course (DOTS) under the Revised National Tuberculosis Control Programme (RNTCP). Drug-resistant TB is a persistent threat, with 490,000 million cases of multidrug-resistant TB (MDR-TB) emerging in 2016 and an additional 110,000 cases that were susceptible to isoniazid but resistant to rifampicin (RR-TB), the most efective first-line anti-TB drug. The countries with the largest numbers of MDR/RR-TB cases. *Causes of Defaulter-*Intolerance,Un-willing for treatment,No improvement,Renal insufficiency*,*Diabetes,Hepatic insufficiency. *REASONS OF DEFAULTER RATES-*Drug side effects such as Nausea/vomiting, Giddiness, Insomnia, Depression/Altered behavior/ Suicidal tendency, Impaired hearing, Hepatitis, Renal toxicity, Visual disturbances, Arthralgia, Cutaneous, Hypothyroidism, Swelling.

II.   METHODOLOGY

STUDY AREA: The study was conducted in Department *of Community Medicine SIMS, & Hapur ,*

STUDY DESIGN: It was a prospective study based on a sample size of 100 MDR patients from (DOTS pilkhua and Hapur)

STUDY PERIOD: The study was conducted from March 2017 to December 2017.

STUDY POPULATION: Defaulter patients whose treatment was interrupted for 2 consecutive months or more without medical approval. a sample size of 100 MDR patients from DOTS center in Hapur.

STATICAL ANALYSIS: This analysis was done on a cohort of patients registered from DOTS Centre at Pilakhuwa and Hapur district. The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 20 statistical analysis software. The values were represetend in number (%) and mean±Sd and χ^2 value.

Table-1: Sexwise Distribution Of Patients According To Their Treatment Facility

Name of the treatment facility	Total No.of patients	Male		Female	
		No	%	No	%
DOTS Centre Pilakhuwa	20	14	14	6	6
District Hospital, Hapur	80	64	64	16	16
Total	100	78	78.0	22	22.0

Thesexwise distribution of the patients was done according to the treatment facility and 20 pateints were seen in Pilakhuwa and 80 pateints were seen in District Hospital Hapur.

Table-2: Distribution Of Study Population According To Treatment Status

SN	Group	Treatment Status	No. of patients	Percentage
1-	Group I	Defaulters	28	28.0
2-	Group II	Non-Defaulters	72	72.0
		Total	100	100

Out of 100 patients enrolled in the study, only 28 (28.0%) were defaulters of DOTS treatment and rest 72 (72.0%) fulfilled their treatment protocol.

TABLE-3: REASONS OF DEFAULT (N=28)

SN	Reason	No. of patients	Percentage
1-	Intolerance	18	36.0
2-	Renal insufficiency	8	16.0
3-	Diabetes	2	4.0
4-	Hepatitis insufficiency	18	36.0
5-	HIV positive	4	8.0
6-	Unwilling	0	0.0
7-	Not important	0	0.0

Most common reason was intolerance of treatment (36%), followed by Hepatitis insufficiency (36%) and Renal insufficiency (16%). Diabetes (4%) and HIV positivity were reasons for (8%) of patients. Unwillingness and non-importance of treatment were not the reasons of default in any of the defaulter patient.

Table-4: Between Group Comparison Of Radiographic And Laboratory Investigations

Variables	Total (N=100)	Default (N=28)		Nondefault (N=72)		Statistical significance	
		No.	%	No.	%	χ^2	p
Infiltrative X-ray	28	28	100.0	0	0.0	5.518	>0.19
AFB positive sputum	100	27	100.0	73	100.0	7.615	>0.01
HIV/HBsAg positive	4	4	14.8	0	0.0	11.265	<0.10
ZN Stain positive	100	27	100.0	73	100.0	16.333	>0.5

AFB positive Sputum and positive ZN stain was observed in all the patients enrolled in the study.Infiltration was found on X-ray of 28 (100%) patients of Group I and none of Group II. Difference in infiltrative X-ray among patients of above two groups was found to be statistically significant.Positive HIV/HBsAg patients of Group I (14.8%) was significantly higher as compared to Group II.

Table 5: Between Group Comparison Of Presenting Complaints

Presenting symptom	Total (N=100)	Default (N=28)		Nondefault (N=72)		Statistical significance	
		No.	%	No.	%	χ^2	p
Cough with Expectoration	100	28	100.0	80	100	0.78	0.180
Weight loss	100	20	100.0	80	100.0	0.456	0.333
Breathlessness	100	20	100.0	80	100.0	0.603	0.106
Loss of appetite	100	2	100.0	80	100.0	0.982	0.385
Chest pain	90		85.2	67	91.8	0.953	0.329

All the patients enrolled in the study (defaulters and non-defaulters) presented with Cough with expectoration, weight loss, breathlessness and loss of appetite. Proportion of patients presenting with chest pain was higher in Group II (91.8%) as compared to Group I (85.2%) but this difference was not found to be significant statistically

III. DISCUSSION

The present study was carried out among MDR-TB patients availing the DOTS facility and to find out the default rate, comorbidity profile and adverse drug reactions in these patients in order to find out whether adverse drug reactions and comorbidities have an impact on default rate. For this purpose, a total of 100 MDR-TB patients were enrolled in the study and were prospectively followed up. The default rate observed in the study was 27%. The default rates among MDR-tuberculosis patients treated under DOTS regimen have shown a considerable variation. In present study intolerance was stated to be the most common reason for default (92.59%) followed by hepatic insufficiency (66.67%) and renal insufficiency (29.63%) respectively. Intolerance to some specific drugs like Kanamycin is a universally observed phenomenon, that is why RNTCP recommends substitution of these drugs with other ones. In present study diabetes was a comorbidty that was stated to be

responsible for default in 7.41% of total cases. In different studies prevalence of diabetes among MDR patients and defaulters have been reported to vary substantially.

IV.   CONCLUSION

The present study was conducted to study the defaulter rates of Pulmonary tuberculosis patients along with the risk of comorbidities of patients in DOTS site of Pilkhua, Hapur and to study the side effects of second line of anti-tubercular therapy. During the period of study, 100 patients of pulmonary tuberculosis were enrolled in the study, out of which 27 (27.0%) defaulted during their treatment while 73 (73.0%) completed their treatment successfully.Rate of default in DOTS treatment by patients of pulmonary tuberculosis was 27.0% in the present set up.Age of patients enrolled ranged between 18 & 76 years and mean age was 40.29 ± 10.47 years, majority were male (77.0%), occupied as labourers (79.0%). Age, Gender and Occupation of defaulter and non-defaulter patients were comparable.Most common reason of default was Intolerance of treatment (92.59%), followed by hepatic insufficiency (66.67%), Renal insufficiency (29.63%) and Diabetes (7.41%). The findings of present study provided useful information regarding the demographic and clinical profile of MDR-tuberculosis patients and their default rate for DOTS treatment. The findings of study showed that in a low resource setting primarily catering to lower socioeconomic strata the default rate is moderately high, and in most of the cases adverse drug reactions were the reason for default. Hence, it is recommended that patients be properly counseled regarding the possible side effects of the drug and their remedies. Moreover, comprehensive health care provision should be integrated in DOTS programme to ensure an absolute compliance and to tackle different side effects associated with DOTS therapy in MDR tuberculosis patients.

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