Research Paper

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Treatment Outcome of Multi Drug Resistant Tuberculosis Patients Treated Under Revised National Tuberculosis Control Programme Category Iv Regimen in Goa

Medical Science

KEYWORDS :

Dr.A.L.Da Costa	Associate Professor, Department of Pulmonary Medicine, Goa Medical College
Dr.Mrs.Durga Lawande	Professor and Head of Department of Pulmonary Medicine, Goa Medical College
Dr.Saravana Ethinder	Junior resident, Department of Pulmonary Medicine, Goa Medical College

ABSTRACT

OBJECTIVE

To evaluate the outcome of multi drug resistant tuberculosis patients treated under RNTCP category IV regimen in Goa.

MATERIALS AND METHODS

A prospective observational study was carried out on MDR TB patients diagnosed and started on treatment as per programmatic management of drug resistant tuberculosis (PMDT) under RNTCP between the period December 2011 to September 2013 at the DOTS Plus site of TB and Chest diseases Hospital, Goa medical college. Patients who were started on treatment were followed up regularly for two years for compliance and adverse drug reactions and their sputum cultures were assessed.

RESULTS

Of the 69 patients included in the study 43 patients sputum culture converted at the third month 2 converted at the 4th month and 1 converted at the 5th month. 14 patients expired, 10 failed on treatment, 34 were declared cured, 7 defaulted, 4 were transferred out.

CONCLUSION

Successful outcome in the treatment of MDR TB patients under CAT IV treatment was low. Adverse drug reactions, longer duration of treatment , home based treatment are major hurdles in successful treatment.

INTRODUCTION

MDR TB is an important public health problem. The estimated number of MDR-TB cases has reached 650,000 globally in 2010 with 99,000 from India.[1]

A TB patient whose sputum is culture positive for *Mycobacterium tuberculosis* and is resistant *in-vitro* to isoniazid and rifampicin with or without resistance to other anti-tubercular drugs based on drug sensitivity testing (DST) results from an RNTCP-certified Culture & DST Laboratory .[2]

TB treatment underwent change with the introduction of chemotherapy over the last 65 years .Drug resistance remains a major hurdle in successfully controlling the disease in the community. Drug resistant tuberculosis requires higher number of drugs and prolonged treatment to successfully cure and prevent future relapse. The drugs used in the treatment are costly and carry greater risk of adverse effects than the drugs used in first line therapy.

MATERIALS AND METHODS

This is a prospective observational study approved by the ethics committee of Goa university.

All patients diagnosed as MDR TB as per RNTCP criteria and registered for treatment at the DOTS Plus site at TB and Chest disease hospital , Goa medical college were included in the study .The study duration was 2 years, from December 2011 to September 2013. Patients were initially admitted at the DOTS Plus site. Treatment was initiated following pre treatment evaluation as per PMDT guidelines. Patients were observed for 1 - 3 weeks and then discharged and ambulatory treatment was arranged at the nearby peripheral health centre.

The standardized regimen consisting of an intensive phase (IP) of 6-9 months with six drugs, namely kanamycin (Km), levofloxacin (Lvx), ethionamide (Eto), pyrazinamide (Z), ethambutol (E), and cycloserine (Cs) given daily and a continuation phase (CP) of 18 months of four drugs, Ofx, Eto, E and Cs. Pyridoxine was administered to all patients.

Patients were then followed up regularly, monitored for adverse effects, sputum collected and sent for culture to intermediate reference laboratory initially after 3 months every month till the end of intensive phase and every 3 months till the end of CP.DOTS Plus site committee meetings held monthly also evaluated patients required specialist opinion. Patients were then declared cured , dead, transfer out, switched to XDR TB treatment as per PMDT protocol.

RESULTS

Of the 69 patients included in the study 43 patients sputum culture converted at the third month 2 converted at the 4th month and 1 converted at the 5th month.6 patients were found to be XDR TB, 11 expired before conversion ,4 defaulted and 2 transferred out and their culture reports were not available.

CULTURE CONVERSION	NUMBER OF MDR TB PATIENTS	PERCENTAGE
3rd month	43	62.3%
4th month	2	2.8%
5th month	1	1.4%
Death within 3 months	11	15.9%
Default within 3 months	4	5.7%
Transfer out	2	2.8%
XDR TB	6	8.6%

Of the 69 patients, 14 patients expired, 10 XDR TB, 34 declared cured, 7 defaulted, 4 transferred out.

OUTCOME	NUMBER OF MDR TB PATIENTS	PERCENTAGE
Cured	34	49.2%
XDR TB	10	14.2%
Death	14	20.2%
Default	7	10.1%
Transfer out	4	5.7%

DISCUSSION

MDR TB patients were started on standardised regimens based on sputum smear for Line Probe Assay (LPA) which detects isoniazid and rifampicin resistance. In this study 8.6% patients did not respond to treatment for 6 months or more and were diagnosed as XDR TB patients. This indicates the need for early testing for drug resistance to second line drugs.

Studies done in Canada[6] and Mumbai[7] which were using individualised treatment regimens based on culture and sensitivity pattern showed higher success rates than in the current study. In the present study patients were on standardised regimens based on LPA result of resistance for isoniazid and rifampicin which are first line drug and patients second line DST were done later resulting in the delay of instituting proper treatment in some patients.

Study done in Ethiopia[5] using standardised regimen but hospital based treatment where patients were kept under isolation until smear conversion or clinical stability showed higher success rate. Hospital based treatment reduced the incidence of default in the study done in Ethiopia. Studies based in Canada[6] also kept patients in isolation. Keeping patients in isolation can reduce the incidence of default and ensure better compliance to treatment, adverse effects would be reported early and managed adequately, and also prevent the spread of disease in the community. In the present study patients were hospitalised only for initial 1 - 3 weeks and then referred for ambulatory treatment. Default rate is high in the current study compared to other studies outside India where patients were hospitalised .Default rate in our study is less compared to a similar study done in Gujarat[4] which was also based on category IV regimen under RNTCP.

This study has the following limitations. The study was an observational study. Patients initially reported to the DOTS Plus provider. Majority of the records were collected through treatment cards. Reasons for default were initially recorded by the DOTS Plus provider and all defaulted patients were subsequently lost to follow up before being evaluated.

WHO pilot study reported a success of 61% in the standardised ambulatory regimen.[3] The success rate noted in the study is less than what is to be expected. Lack of early diagnostic testing for 2nd line drugs, higher pill count, poor tolerance, adverse effects , home based treatment, lack of efficient coordination of health care personnel are all major limitations in successfully treating and controlling the disease in the community.

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