

Outcome Results of Programmatic Management of Drug Resistant Tuberculosis in 84 Patients From North Coastal Andhra Pradesh

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Abstract

Background and Objectives: In order to achieve “universal access” targets Revised National Tuberculosis Control Programme (RNTCP) control program is deploying rapid diagnostics like line probe assay (LPA), liquid cultures and Gene Xpert for rapid diagnosis of multidrug-resistant tuberculosis (MDRTB). This study is undertaken to highlight the advantages of LPA in early detection of MDRTB and initiation of Category (CAT) IV regimen. It also analyses treatment outcome results of 84 patients of MDRTB under programmatic management of drug-resistant tuberculosis (DR-TB).

Materials and Methods: A retrospective analytic study of 84 patients of MDRTB belonging to 3 districts of North coastal Andhra Pradesh, admitted at DR-TB center, Government Chest Hospital, Visakhapatnam between May 2011 and December 2011. The demographic details, meantime delays for diagnosis and treatment, sputum smear and culture conversion results, adverse drug reactions (ADR), treatment outcome results are analyzed.

Results: The mean time interval for MDR diagnosis was 6.144 days in 82 patients. There is a mean delay of 13.32 days in 79 patients in initiation of CAT IV regimen. Cure rate was 53.57%, default rate 13%, the death rate 25% and ADR frequencies 33% and none had extensive DR-TB.

Conclusion: Rapid diagnostics like LPA will reduce the delay in MDR diagnosis and treatment. This will reduce the death rate in long-term. Default rate can be reduced by intensifying health education, strengthening family support and improving nutritional status.

Keywords: Line probe assay, Multidrug-resistant tuberculosis, Programmatic management of drug-resistant tuberculosis, Universal access

INTRODUCTION

India is home to over 25% of world’s tuberculosis (TB) cases and ever since government of India started implementing DOTS Strategy under Revised National TB Control Program (RNTCP) since 1997, the country has come a long way.¹ The entire country is covered with DOTS by 2006 and treatment success rate improved since then. However, the emergence of multidrug-resistant tuberculosis (MDRTB) has become a challenge all over the world, and it is creating an obstacle to the effective management of TB in our country as well.

World Health Organization (WHO) estimates that between 2,20,000 and 4,00,000 MDRTB occurred among TB cases notified in the world in 2011. About 60% of these occurred in Brazil, Russian Federation India, China, and South Africa alone (BRICS Countries). India has the second highest burden of MDRTB cases following China.² RNTCP started a WHO recommended DOTS PLUS program in a phased manner for the systematic treatment of MDRTB in 2007. By Feb 2013, programmatic management of drug-resistant tuberculosis (PMDT) services were available in 35 states of the country (including Union Territories), 638 districts covering a population of 1089 million (92%)

and were rapidly scaled up to include remaining districts by 24th March 2013.³

As per the drug resistance surveillance surveys in Gujarat, Maharashtra and Andhra Pradesh, estimated proportion of MDRTB is 2.1% (1.5-2.7%) in new TB cases and 15% (13-17%) in previously treated cases.⁴ Global data show that 32% of relapse cases actually have MDRTB.

Until recently, RNTCP relied on conventional Lowenstein Jensen culture (LJC) and drug susceptibility tests (DST) for the diagnosis of DRTB cases. By December, 2009 there were only 14 such laboratories across the country, validated and certified by RNTCP for conducting LJC and DST, where the mean time to detect DRTB was 3-4 months. Newly developed molecular-based genotypic methods have advantages over conventional phenotypic cultures in terms of both accuracy and turn-around time. A multisite validation study conducted at three-state level reference laboratories in different regions in India by foundation for innovative diagnostics (FIND) showed that in addition to a higher proportion of interpretable results with line probe assay (LPA) compared to LJC and DST (94% vs. 80%) it demonstrated an overall sensitivity and Specificity of LPA for detection of resistance to rifampicin which was high at 96% and 99% respectively.⁵ These findings are similar to a large meta-analysis by Ling *et al.* in 2008.⁶ Hence it is concluded that routine use of LPA can not only reduce the time to diagnose rifampicin and/or isoniazid resistant TB, it can also enable earlier initiation of the patients on standard drug regimen. Thirdly it reduces the chances of transmission of DR strains since a smear positive patient can infect 10-15 persons in a community in a year and can remain infectious for another 2-3 years if left untreated.

In the dynamic transmission model of TB epidemic in India by Suen *et al.*, important implications of India's transition from a treatment generated MDRTB epidemic toward the transmission generated disease are well discussed.⁷ It is observed that improving non-MDRTB cure rates to avoid generating new MDR cases will provide substantial non-MDRTB benefits, but will become less effective in reducing MDRTB prevalence over time because more cases will occur from direct transmissions. It is estimated that by 2015, 42% of new MDR cases are transmission generated. Reducing transmission generated cases requires rapid and accurate MDRTB diagnosis, which is why rapid molecular-based tests are becoming increasingly important. Coinciding with RNTCP Phase III a new strategy of a comprehensive national strategy plan has been developed for 2012-2017 and its new objective is universal access to quality diagnosis and treatment for all TB patients in the community. In order to achieve the

targets under universal access by 2015, the program is deploying rapid diagnostics such as light-emitting diode microscope, LPA, automated liquid cultures, Gene Xpert for rapid diagnosis of MDRTB.

Under Phase III, PMDT services were made available for three districts in North Coastal Andhra Pradesh (NCAP) from May, 2011 and for the first time in Andhra Pradesh, MDRTB is diagnosed using LPA as a diagnostic tool. The present study analyses the treatment outcome results of an MDRTB cohort of 84 patients under PMDT guidelines. The patients belonging to three districts of NCAP were admitted at the drug-resistant tuberculosis (DR-TB) center, Government Chest Hospital for Communicable Diseases (GHCCD) in the first 8 months after its inception. It also focuses on the advantages of genotype MTBDR plus LPA over the conventional solid culture techniques in the detection of resistance to rifampicin and Isoniazid.

MATERIALS AND METHODS

In the present study, retrospective analysis was done on a cohort of 84 MDRTB patients who were admitted at the DR-TB center, in the GHCCD, Andhra Medical College, Visakhapatnam, during the period from May 2011 to December 2011.

All the 84 patients consecutively enrolled in the study were diagnosed with MDRTB at the IRL, Hyderabad and RNTCP certified C&DST Laboratory, Visakhapatnam, located in the building of GHCCD. Prior to the diagnosis, all the patients were MDRTB suspects as per the RNTCP strategy at the time of the study, i.e., patients who failed category (CAT) I regimen and CAT II patients whose sputum was positive at the end of 4th month or later. The patients belonged to three districts in NACP, Visakhapatnam, Vizianagaram and Srikakulam. The two-sputum samples of the MDR suspects who were sputum positive were collected in Falcon tubes and transported in cold chain from the respective designated microscopy Centre (DMCs), some to RIL, Hyderabad and some to the C&DST Laboratory in our hospital. The C&DST Laboratory is attached to AMC and supported by FIND, WHO and Central RB Division (CTD) through state, and its first accreditation was done in 2011. All the sputum positive samples of the MDRTB suspects were subjected to LPA and results were available in 2-3 days. When the results were inconclusive, the culture was repeated on LJ culture medium, and the culture isolate was tested with LPA. All the follow-up cultures were also tested on LJ medium. All the confirmed MDRTB cases were traced, counseled and referred to DR-TB center, GHCCD for pre-treatment assessment and initiation of CAT IV regimen.

As per the program guidelines, all the patients underwent thorough clinical evaluation including height and weight recording, complete blood count, blood sugar, liver function tests, renal function tests, thyroid stimulating hormone, urine examination, pregnancy test in women of childbearing age group and HIV testing after counseling and Chest X-ray examination.

During the stay at the DR-TB center, which is a 24 bedded ward (12 for males and 12 for females) with air-borne infection control measures in place as per the guidelines, the patients were initiated on CAT IV regimen consisting of 6 (9) Km Ofx Eto Cs Z E/18 Ofx Eto Cs E. Patients were discharged 1-2 weeks after initiation of CAT IV. Trained DOTS Providers arranged through concerned DTO administered the drugs under supervision, counseled the patients and family and took care to identify and refer them to the DTO/DR-TB center in the event of adverse drug reactions (ADRs).

Follow-up sputum smear and culture examination was done at the end of the months 3, 4, 5, 6 and 7 and at 3 monthly intervals from 9th month onwards till the completion of treatment (9, 12, 15, 18, 21, 24 months). The sputum smear microscopy was done at the concerned DMC and culture was done on LJ medium at C&DST Laboratory, GHCCD. If any of the cultures in the last 3 quarters was positive, it was followed by monthly culture in the following 3 months. Based on the culture reports of 4th, 5th, 6th months, the Intensive Phase (IP) was extended to 1-3 months.

After discharge from DR-TB center, the respective DTOs reviewed the patients at monthly intervals during IP and 3 monthly intervals during CP until the end of the treatment. Patients were evaluated for clinical improvement, weight changes and possible adverse reactions.

Treatment Outcome results are classified as follows: Cure, defaulter, death, treatment failure, treatment completed, and still on treatment.

Cure

A patient who has completed treatment and has been consistently culture negative (with at least 5 consecutive negative results in the last 12-15 months). If one follow-up positive culture is reported during the last three quarters, patient will still be considered cured provided this positive culture is followed by at least three consecutive negative cultures, taken at least 30 days apart, provided that there is clinical evidence of improvement.

Defaulter

A patient whose treatment was interrupted for two or more consecutive months for any reasons.

Death

A patient who dies for any reason during the course of drug-resistant TB (M/XDR-TB) treatment.

Treatment Failure

Treatment will be considered to have failed if two or more of the five cultures recorded in the final 12-15 months are positive, or if any of the final three cultures are positive.

Treatment Completed

A patient who has completed treatment according to guidelines but does not meet the definition for cured or treatment failure due to lack of bacteriological results.

Still on Treatment

An M/XDR-TB patient who, for any reason, is still receiving their treatment at the time of the submission of the treatment outcome report.

RESULTS

A total of 84 cases of confirmed MDRTB cases were admitted at DR-TB center, GHCCD, Visakhapatnam between May 2011 and December 2011. Of the 84 cases, 65 were Males, and 19 were females. 63 patients belonged to the age group <45 years, the youngest being 14-year-old. 47 patients lived in urban areas, and 37 belonged to rural areas. The number of patients belonging to Visakhapatnam, Vizianagaram and Srikakulam, were 40, 27, 17 respectively (Table 1).

Of the 84 patients, 16 were CAT I Failure and 68 were CAT II failures. The resistance pattern on LPA showed that 58 patients were resistant to R and H, and 26 patients were

Table 1: Demographic data and resistance patterns

Characteristics	Data
Age (years)	
<30	32
30-45	31
>45	21
Residence	
Urban	47
Rural	37
Sex	
Males	65
Females	19
Ratio	3:1
Weight bands (kg)	
16-25	2
26-45	37
>45	25
Resistance patterns on LPA	
Rifampicin (H) only	26 (30%)
Rifampicin and isoniazid (R and H)	58 (70%)

LPA: Line probe assay

resistant to R alone. In 2 cases due to inconclusive LPA results, LJ Inoculations and retesting of culture isolates with LPA was done.

Two patients belonged to the weight band of 16-25 kg, 37 patients to 26-45 kg, and 25 patients to >45 kg.

Definition of smear conversion, culture conversion, time to culture conversion.

Smear Conversion

Patients will be considered smear converted after having two consecutive negative smears taken at least 1 month apart (Table 2).

Culture Conversion

Patients will be considered culture converted after having two consecutive negative cultures taken at least 1 month apart.

Time to Culture Conversion

It is calculated as the interval between the date of MDRTB treatment initiation and the date of the first of these two negative consecutive cultures (the date that the sputum specimens are collected for culture should be used).

The mean time taken from sputum sample collection to MDR confirmation at C&DST Laboratory at GHCCD is 6.144 days (range 1-25 days) in a total of 82 cases. In 2 cases due to inconclusive results on LPA and LJ Culture and reanalysis the time taken was 40 days and 37 days.

For 79 cases, after MDRTB confirmation, CAT IV Regimen initiation at DR-TB center was done in the mean time of 13.32 days (range of 7-30 days). 5 cases had a mean delay of 100 days due to patient’s unwillingness to be started on the regimen, lack of family support, etc.

At the end of 3rd month, sputum smear conversion occurred in 62 patients, and it remained positive in 11 patients. Culture conversion was observed in 65 patients and eight remained cultures positive. By the end of 3rd month, Deaths and defaulters were nine and two respectively.

Table 2: Smear and culture conversion at 3rd and 6th months

Characteristic	By the end of 3 rd month (%)	By the end of 6 th month (%)
Smear converted	62 (74)	55 (65)
Smear positive	11 (13)	7 (8)
Culture converted	65 (77)	56 (66.6)
Culture positive	8 (9.5)	6 (7.1)
Defaulters	2 (2)	5 (5.9)
Deaths	9 (10.7)	7 (8.3)

At the end of 6th month, smear conversion was observed in 55 patients and smear was still positive in 7 patients. At the same time, culture conversion was seen in 56 patients, and it remained positive in 6 patients. Of these 6 patients, three converted by 7th month, one by 9th month, one by 12th month and the 6th patient died. By the end of 6th month, deaths and defaulters were seven and five respectively (Figure 1).

Out of the 56 patients who were culture converted by the end of 6th month, one patient became culture positive by the 12th and 15th months. He was declared as “treatment failure” and his sputum sample was sent to national reference laboratories, National Institute for Research in TB Chennai, for second line DST. He was found to be resistant to ofloxacin and sensitive to Kanamycin and hence the DR-TB center Committee replaced ofloxacin with moxifloxacin.

Comorbidities associated in the present cohort were diabetes mellitus in 9 patients and HIV disease in 1 patient. Out of the 9 patients with DM, culture conversion occurred at the end of 3rd month in 8 patients and at the end of 4th month in 1 patient. During the follow-up months, 1 patient defaulted and one patient died after 9th month. The single patient with HIV also got culture converted by 3rd month, but the patient died during follow-up after 11 months.

During the course of DOTS PLUS treatment, 28 cases were referred to DR-TB center Committee for management of ADR. Admission was done only in those cases where Observation and/or change of regimen were required. Minor skin reactions like pruritic rash in 2 cases and acne form lesions in one case were observed. Three patients were admitted for breathlessness, and one for hemoptysis, all of them were symptomatically managed. Three patients had joint pains and gastrointestinal symptoms such as nausea, vomiting, diarrhea, dysphagia were observed

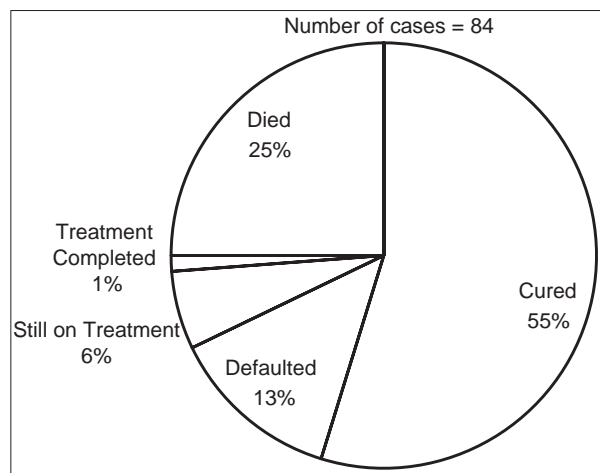


Figure 1: Treatment outcomes of 84 patients enrolled in the study

in three patients and were managed symptomatically. Peripheral neuropathy was observed in one patient in whom ethionamide was NaPAS. Five patients presented with tinnitus and loss of hearing. They were examined by ENT surgeon and audiometry was done. Kanamycin was replaced by NAPAS in these patients. None of the patients had severe ADR necessitating the total cessation of treatment.

The treatment outcome results were analyzed. 46 out of the 84 cases (53.57%) were cured. Of these cases, one case was a treatment failure but eventually turned "Cured." 21 patients died, and 11 defaulted. All the defaulters were males. Five patients were "Still on Treatment" and one case "Treatment Completed." None was diagnosed with XDRTB.

DISCUSSION

In the present study of 84 patients, males had a predominance of 77%. 63 out of 84 (75%) belonged to productive age group of <45 years. In our present study, 16 out of 84 (19%) were CAT I Failure and the rest, CAT II Failure. In a similar study by Visakha *et al.* the CAT I/III failures were 12.69%, and the rest were CAT II failures.⁸

Majority (37) of the patients in the present study belonged to weight band of 26-45 kg followed by >45 kg weight band.

In the present study, LPA results showed a mono resistance pattern to rifampicin in 26 out of 84 patients, and the rest were resistant to both H&R. The mean time interval from the specimen collection to obtaining LPA result was 6.144 days (in 82 cases). After confirmation of MDRTB, there was a mean delay of 13.32 days in 79 cases in the initiation of CAT IV regimen at DR-TB center. Five cases had a mean delay of 100 days due to patient's reluctance and other personal reasons.

In a multisite validation study of LPA by Raizada *et al.*, the average delay was 11 days (Range 1-76 days).⁵ In another DOTS PILOT study by Singla *et al.*, there was a mean delay of 5 months in establishing a diagnosis of MDRTB when LJC and DST were used.⁹ When BACTEC was used, the mean delay was reduced to 2.8 months. In the same study, after diagnosis of MDRTB there was a mean delay of 3.3 months in initiating treatment. Hence the use of LPA can substantially reduce the time to diagnosis of MDRTB, and it enables earlier commencement of standard treatment, thereby preventing transmission of MDRTB strains in the community.

Different studies have shown that sputum culture conversion rate varied from 74% to 92%. In the present study 65 of 84 (77%), were culture converted by the end

of 3rd month 56 of 84 (66.6%) by the end of 6th month. It shows that the majority become non-infectious by end of 3rd month. The 5 patients who remained culture positive by the end of 6th month converted in the later months (7-12th months).

By the end of 3rd month, the deaths and defaults were 9 and 2 cases respectively and by the end of 6th month they were 7 and 5 cases. It shows that most deaths (16 of 21) occurred before 6 months. Since this study had the first batch of pooled up patients in the North coastal districts who were waiting to be diagnosed and treated for MDRTB, the early deaths indicate extensive damage to lungs of the patients. Defaulter rate (7 of 11) too was more in the first 6 months.

ADR were reported in various studies with a frequency of 19-72%. The present study had 28 cases referred to DR-TB center for the management of ADR (33%). Only 6 patients (7%) had major ADR. In one patient with ethionamide induced peripheral neuropathy, the drug was replaced by NAPAS and in 5 patients with kanamycin induced 8th nerve toxicity, the drug was replaced by NAPAS.

Although psychotic reaction due to cycloserine was observed in a significant number of cases in the Singla *et al.* and Visakha *et al.* studies, where the drug had to be terminated, the present study did not have any patient with such psychotic or depressive reactions.

Analysis of treatment outcome results showed that cure rate was 53.57%. Various studies worldwide demonstrated a cure rate varying from 38-100%. Our cure rates are lower when compared to the 66% and 61% of Joseph *et al.* and Singla *et al.* studies respectively.^{9,10} Yet our Cure Rates are higher than the 39% of Visakha *et al.* and 37% of Thomas *et al.* and 39% of Jain *et al.*^{8,11,12} The defaulter rate of 11 of 84 (13%) and the death rate of 21 of 84 (25%) in the present study explains the lower cure rates (53%) (Table 3). The defaulter rate and death rates in our present study are similar to many other studies across India. When enquired into the reasons for defaulting, it is observed that the defaulted patients lacked family support, were

Table 3: Outcome of MDRTB in different studies a comparison

	Cure rate (%)	Default rate (%)	Death rate (%)
Present study	54	13	25
Thomas <i>et al.</i>	37	24	13
Singla <i>et al.</i>	61	18	19
Visakha <i>et al.</i>	39	26	21
Joseph <i>et al.</i>	66	13	8
Jain <i>et al.</i>	39	23	19

MDRTB: Multidrug-resistant tuberculosis

reluctant to consume a large number of pills for a period of 24 months and sometimes migration was the cause. Some had very low nutritional status and did not want to go on with the treatment and attributed minor adverse effects to the drugs.

The diabetics and HIV patients in the present study had culture conversion by 3rd month except in one patient. It indicates that the CAT IV regimen is equally efficient in MDRTB patients with comorbidities. It is also observed that none of the females defaulted although the death rates are almost equal in both sexes. The zero-default rate in female patients is probably because of absence of risk factors like smoking and alcoholism and also women in general are believed to be more vigilant and compliant with drugs.

The overall treatment success rate is 48% according to the data available from 60 countries across the world.² The global target of treatment success rate is 75% which can be achieved with rapid scale-up of RNTCP services and more number of certified laboratories adopting rapid diagnostic methods. RNTCP strategy of case detection also has changed with the new A, B, C criteria for an MDR suspect.¹³ This will also help in the detection of disease in early stage before permanent lung damage occurs.

To make the patients more knowledgeable about their condition and for better adherence, strong health education to the patient as well as the family members is highly important. More intense monitoring and early identification and management of ADR also help to reduce default rates which will have an impact on the success rate.

This study had few limitations that it is a small cohort, and it was in the early months of PMDT services at our hospital. Therefore, the study group was largely made up of pooled up patients with MDRTB, which may have had an impact on the treatment outcome. There were also some initial operational difficulties because of which this study lacks data of BMI, radiological features and history of contact details.

CONCLUSION

The cure rate with PMDT in the present study is 53.57% which is above overall treatment success rate (48%). The global target of 75% can be achieved with widespread use of rapid diagnostics like LPA, which will reduce the time for diagnosis and treatment of MDRTB. This will help in reducing death rate in the long term which will have an

impact on success rate. The default rate can be further reduced by intensifying health education, improving family support and nutritional status.

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