



DIAGNOSTIC AND TREATMENT PROTOCOL ADOPTED BY PRIVATE PRACTITIONERS OF SURAT CITY FOR DRUG RESISTANT TUBERCULOSIS PATIENTS

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ABSTRACT

Introduction: This study explores the practices adopted by Private Practitioners for diagnosis and management of Drug Resistant Tuberculosis patients in Surat city of Western India.

Methodology: In this descriptive cross sectional study of Private Physicians of Surat city were selected randomly from IMA Surat member list. A pre-test questionnaire including Profile of the doctor, Profile of patients suspected for MDR TB, Diagnostic & Treatment practices and Follow up issues was used to collect data. Data Analysis was done using Epi-info software calculating descriptive statistics.

Results: Most common investigative methods used by private physicians to diagnose MDR TB were sputum microscopy, x-ray chest and sputum culture. Commonly used second line drugs for MDR TB patients were Fluoroquinolones, Aminoglycosides and Ethionamide. Nearly three fourth physicians preferred 4 or more drug combination for MDR TB treatment. Most of them preferred 2 or 3 second line drugs in their prescriptions. Common investigations preferred by them during follow up were Sputum AFB, Culture and Chest X-Ray.

Conclusion: Compliance to recommended standards of MDR TB management was common among the private physicians but quite a few were unacceptable in context of WHO recommendations. There is need to streamline these protocols according to the general guideline for MDR TB management.

Keywords: Private Practitioners, MDR TB, Protocols

INTRODUCTION

India accounts for the fifth of the global burden of Tuberculosis (TB).¹ The national Annual Risk of Tuberculosis Infection is 1.5%¹, and the prevalence of TB as per the recent estimate by WHO is 2.186 million.^{2,3} WHO estimated TB mortality in India as 276,000 (24/100,000 population) in 2008.¹

In recent years, the emergence of drug resistant TB, particularly Multi Drug Resistant TB (MDR-

TB), has become a significant public health problem and a major obstacle to programme managers for effective TB control.⁴ Patients with MDR-TB can only be treated with costly second-line anti-TB drugs, which are less efficacious and more toxic. Unregulated use of the second line drugs can lead to emergence of Extensively Drug Resistant TB (XDR-TB) from MDR TB. In 2007 there were an estimated 0.5 million cases of MDR-TB globally, among them India ranked first with 131000 cases.⁵ The problem of MDR and XDR TB

in India increases the possibility that the current TB epidemic of drug susceptible TB will be substituted with a form of TB with severely limited treatment options.¹

In spite of a significantly strengthened Revised National TB control programme (RNTCP) in India, 50–80% of TB patients still pursue care at private sectors. However TB treatment offered in the private clinics are substandard and varies widely.^{6–8} Presently our RNTCP programme scarcely runs in the private setup and therefore MDR-TB patients seeking medical care at private hospitals invariably do not get access to the diagnostic (culture and drug sensitivity) and treatment (DOTS-plus) services provided by the government. It is crucial that private providers follow RNTCP guidelines for treatment of TB and MDR-TB, as the treatment with a standard regimen using quality-assured medication administered under direct observation can be expected to reduce the chance of second-line drug resistance. Several attempts have been made by RNTCP to involve the private practitioners in TB care and control.^{9,10} However, they comprise only a minute of the huge private health sector in this country and their exact contribution in identifying and treating TB cases is not known.

This study explores the practices adopted by Private Practitioners for diagnosis and management of Drug Resistant Tuberculosis, protocols implemented by them for assuring treatment adherence and treatment completion in MDR TB patients in Surat city of Western India with the aim of improving upon their existing practices so as to meet the RNTCP guidelines.

METHOD

This is a descriptive cross sectional study of Private Physicians/Chest Physicians (MD) of Surat city. Sampling universe of Private Physicians was generated from multiple data sources including IMA Surat branch member list. From this universe Private Physicians were selected randomly using random number table. An attempt was made to cover at least half of the registered Physicians working in the private sector of Surat city to be included in the study. In case the selected Physicians were unavailable or not consented to participate, next Physicians were included from the sampling universe. This will continue till the desired sample size achieved.

The doctors were interviewed after obtaining their informed consent. Only post graduate doctors having qualification either in Internal Medicine or TB & Chest Disease were included in the study. Those who had never provided services to the Drug Resistant TB patients were excluded from this study. A pre-test questionnaire including Profile of the doctor, Profile of patients suspected for MDR TB, Diagnostic & Treatment practices and other information like Follow up & complications was used to collect data. Data Analysis was done using Epi-info software calculating descriptive statistics (means, proportions and percentages).

The purpose for seeking information was explained in detail to individual practitioner. The data collected was presented as an aggregate and was not linked to any individual in the study. The data obtained during the study was securely held and confidentiality was maintained at every level. The study was also approved by Institutional Ethical Committee of our institute.

RESULTS

Total 68 eligible physicians were contacted and distributed questionnaires. However we could get only 57 questionnaires back which give response rate of 83.82%.

Mean age of the participant doctors was 42.9 years with Standard deviation of 8.5 years. Among the study group more than half doctors had clinical experience above 10 years. Mean clinical experience was 14.9 years with SD 9.1 years which indicate that the study groups had good clinical exposure. All physicians had experience of managing drug resistance TB patient.

All physician included in the study were asked about various investigative methods preferred by them for the diagnosis of suspected drug resistant tuberculosis patients. Data shown in Table 1 indicate that use of more sophisticated techniques were less preferred. This may be due to availability as well as cost of the investigations.

Almost all physicians preferred to send sample to the private laboratories for the investigations. However, almost half of the physicians were not aware about IRL accreditation of the laboratory where they prefer to send samples.

Drug susceptibility testing is also important investigation before starting second line drugs. It was preferred by almost all physicians (94.74%) before starting first line drugs. However, only half

physicians (55.56%) preferred doing drug susceptibility testing for second line drugs. Almost all physicians send samples to private laboratory for drug sensitivity testing.

Treatment practices accomplished and preferred by the participant physicians were also assessed. TB and MDR TB need combination drug therapy which is very complex and long duration in nature. Many different ranges of drug combinations are available in market which may not be equally effective. WHO and other agencies like RNTCP recommend and provide standard treatment regimen (STR) based on the available evidence. However, more than one third physicians (36.84%) do not believe in STR and prefer to decode drug regimen on case to case basis.

Among 57 physicians only 33 (57.89%) always preferred culture based practice to select drugs for MDR TB patients. Table 2 shows list of drug preferred by surveyed physicians for treatment of MDR TB patients. Most commonly used second line drugs for MDR TB patients were Fluoroquinolones (100%), Aminoglycosides (94.74%) and Ethionamide (94.74%).

More than 10% physicians always preferred hospitalization for treating MDR TB patient. Mean duration of hospitalization was 7.1 days with standard deviation of 4.6 days. On an average patients were called for monitoring and follow up at the interval of 19.4 days with standard deviation of 8.2 days. Most common investigations preferred by the physicians during Monitoring and Follow up were Sputum AFB (89.47%), S.Creat/Bilirubin/TSH (78.95), Culture (42.11%) and Chest X-Ray (42.11%).

Table 3 shows that nearly three fourth (70.2%) physician preferred 4 or more drug combination for MDR TB treatment. More than 78% physicians preferred at least 18 months duration drug therapy for treating MDR TB patient.

Most of the physicians prefer two or three second line drugs in the prescription. Table 4 shows number of second line drugs preferred by physicians in their prescription for MDR TB patient. Table 5 shows various criteria used to assess whether the therapy was effective or not. Many physician prefer to use clinical criteria only.

Poor treatment compliance was the major adherence issue noted in MDR TB patient by more than one third of physicians (37.50%). Almost 90% physicians advised high protein diet as a supportive treatment to their patients. Other specific

treatment along with MDR TB treatment was Proton Pump Inhibitors (42.86%) and Multivitamin tablets (38.09%).

Table 1: Investigative Methods used by Private Practitioners to diagnose suspected MDR TB patients (multiple answers) (n=57)

Methods	Frequency (%)
Sputum smear for AFB by Z/N stain	51 (89.47)
X ray chest	51 (89.47)
Sputum Culture for AFB (Solid/Liquid Bactec/MGIT)	45 (78.95)
Tuberculin testing	15 (26.32)
CT Scan guided intervention & Culture	15 (26.32)
Biopsy & tissue Culture AFB	9 (15.79)
PCR Based Investigation (LPA)	12 (21.05)
Gen X-pert	15 (26.32)

Table 2: Drugs commonly used for adult MDR TB patient (multiple answers) (n=57)

Drugs	Frequency (%)
Pyrazinamide	45 (78.95)
Ethambutol	36 (63.16)
Ethionamide	54 (94.74)
Cycloserine	27 (47.37)
Ofloxacin/Levofloxacin/Moxifloxacin	57 (100.00)
Kanamycin/Amikacin/Gentamycin	54 (94.74)
Azithromycin	15 (26.32)
PAS, Linezolid, Ritabutine	15 (26.32)

Table 3: Number of drugs combinations preferred by physicians for their MDR TB patients (n=57)

Drug combinations	Frequency (%)
Separate drug prescription	5 (8.8)
2 drugs fixed dose combination	1 (1.8)
3 drugs fixed dose combination	11 (19.3)
4 drugs fixed dose combination	28 (49.1)
More than 4 drugs fixed dose combination	12 (21.1)

Table 4: Number of second line drugs in prescription by physicians for MDR TB patient (n=57)

Number of second line drugs in prescription	Frequency (%)
One	4 (7.0)
Two	22 (38.6)

Three	24 (42.1)
Four	4 (7.0)
Five	3 (5.3)

Table 5: Criteria for judgement of the condition of treated patients is improved (Multiple answers) (n=57)

Criteria for judgement	Frequency (%)
Symptoms improved	51 (89.47)
Weight gain	51 (89.47)
Appetite improved	48 (84.21)
Sputum smear conversation	51 (89.47)
Culture conversion	33 (57.89)
Chest X-Ray Improvement	18 (31.58)

DISCUSSION

Private sectors are an important part of the TB treatment background. This study represents the detailed overview of the private TB drug practice in Surat city of western India with the special concern to expanding population of MDR-TB patients. A DOTS-plus strategy has been implemented in a phased manner in India and its seven year pilot experience was quite promising.¹¹ However, this still leaves uncovered the large numbers of MDR-TB patients who seek out private health setup in an effort to cure their MDR-TB. These private practitioners are frequently of varying standards, many of them are inefficiently qualified to deal with this problem.¹² There are no clear nationwide guidelines in the huge private sector to overcome this threat.

Sputum microscopy and sputum culture are found to be more cost effective than serological testing in the Indian setting.¹³ In our study also most common investigative methods used by physicians to diagnose suspected MDR TB patients were sputum microscopy (89.47%), x-ray chest (89.47%) and sputum culture (78.95%). Our data on use of sputum microscopy are reliable with the findings of other recent studies, which report a large proportion of private physicians using sputum microscopy as a preliminary diagnostic means.^{14,15} Although use of serological testing for diagnosis of MDR TB is inaccurate, widespread use of these tests was reported in data collected from 22 high burden countries including India.¹⁶ However in our study not a single physician preferred serological testing in their patient for diagnosing MDR TB. The use of personalised treatment, based on reliable Drug Susceptibility Testing (DST) is essential if these patients are to be successfully cured. In our study nearly half

physicians preferred doing Drug Susceptibility Testing for second line drugs.

The suggested number of drugs needed to treat MDR TB is a subject of controversy. The American Thoracic Society (ATS) recommends four to six drugs for the management of MDR-TB.¹⁷ However the WHO recommends at least four drugs to be included in treatment schedules.¹⁸ The definitive regimens, determined on the basis of the results of drug susceptibility, contained a minimum of five drugs and continued for at least 18 months.¹⁹ The agreement is that more drugs may be required for more serious patients or whose DST profile is adverse. Thus, Group 4 and newer drugs like linezolid, PAS (Para Amino Salicylic acid) and Ritabutine were commonly resorted to in order to make up the mandatory number of drugs necessary for an effective regimen. In our study 26% of physicians preferred these novel drugs in their treatment regimens. Also it was observed in our study group that nearly three fourth physician preferred 4 or more drug combination for MDR TB treatment and most of the physicians (80.7%) preferred two or three second line drugs in their prescriptions.

Quinolones are broad spectrum antibacterial agents which are the most frequently prescribed group of antibiotics across India. All efforts should be made to incorporate a quinolone in treatment regimen for MDR TB as quinolone use has been recognised to be a good indicator of successful treatment outcome.²⁰ In our study almost all physicians preferred to use quinolones in their treatment regimens. Also it was observed that Moxifloxacin was the most frequently used quinolone in our study group. This was due to the fact that Moxifloxacin has a better pharmacological profile with its relatively long half-life which suggests this agent may be an ideal anti-TB drug.²¹ Susceptibility to Pyrazinamide, Ethionamide, Kanamycin and PAS was reserved in larger number of MDR TB isolates. Thus, if a pragmatic treatment regimen is scheduled (where culture and sensitivity is not accessible) these drugs should preferably be incorporated. The use of Aminoglycosides has also been suggested, as injectable therapy is known to be a forecaster of positive treatment outcome. In our study group almost 95% physicians preferred Aminoglycosides in their treatment regimen.

It was observed in our study that more than 10% physicians advised hospitalization to their patients with mean duration of hospital stay of 7 days. The cost of hospitalizing patients for

MDR-TB as practiced in our study would be unreasonable as several studies have shown that MDR-TB can be effectively treated on an outpatient basis.²² Patients getting treatment for MDR-TB should be carefully followed up by clinical (fever, cough, sputum production, weight gain), radiological (chest X-Ray), laboratory (erythrocyte sedimentation rate) and microbiological (sputum smear and culture) parameters to assess the response to treatment. In our study most common investigations preferred by the physicians during Monitoring and Follow up were sputum AFB, S.Creat/ Billirubin/ TSH, culture and chest X-Ray. Common criteria used by them to judge the improvement of treated patients were symptoms improved; weight gain; appetite improved; and sputum smear conversion.

Drug Resistant Tuberculosis is a degenerative disease. Therefore, nutritional support has a significant role in the care of patients with MDR-TB.²³ In our study it was observed that almost 95% physicians advised high protein diet to their patients. Attitude of health care staff is very essential in determining treatment adherence²⁴ and most private practitioners would be observing for means to build relationship with their patients. Directly Observed Treatment (DOTS-plus) for MDR TB can be promoted as the preferred method; however physicians who can document and account treatment adherence by other methods should also be supported. In our study more than half physicians come across the adherence related issues. To overcome these issues physicians called their patients for follow up at the mean interval of 19 days with standard deviation of 8 days.

Several studies have revealed a need for periodic updating and continuing education for private physicians. In India, Uplekar and colleagues emphasised the need to educate both private practitioners and their patients with MDR tuberculosis.²⁵ In Vietnam, Viet Co found that knowledge about MDR tuberculosis diagnosis and treatment was poor among both private and general Doctors, and suggested increased training in drug resistant tuberculosis case management.²⁶ Here in our study group almost all physicians had attended CME/ Training/ Workshop related to MDR TB in last three months by different means like conferences organized by government hospitals, private hospitals or IMA (Indian Medical Association).

CONCLUSION

Treatment of MDR-TB is a challenge which should be commenced by skilled clinicians at centres furnished with reliable laboratory service for mycobacterial culture and sensitivity testing. From this study we conclude that compliance to recommended standards of MDR TB diagnosis and treatment was common among the private physicians but quite a few were unacceptable in context of WHO recommendations for MDR TB treatment. There is need to streamline these protocols according to the general guideline for MDR TB management. Physicians also need to be encouraged for drug sensitivity testing before starting the treatment. Monitoring and Follow up should be made evidence based instead of only using clinical criteria. Active participation of private practitioners in service delivery under public-private partnerships through regular training and sensitization may diminish the prescription of unnecessary diagnostic tests and use of ridiculous treatment practices.

LIMITATIONS

Certain limitations must be considered in interpreting our findings. This study was conducted in an urban area and among Private Physicians having MD degree; therefore our results may not be generalized to the practitioner of rural areas or other categories of doctors (General practitioners/non-allopathic doctors) treating MDR TB patients which may have considerable differences in diagnostic and treatment practice for MDR TB patients.

The information regarding diagnostic and treatment practices provided by the physicians was not verified. The data was captured through self-administered questionnaire only which has its own merits and demerits. However we could find it is the best way to collect desired information.

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