

Private Allopathic Medical Practitioners' Approach to Management of Multi-drug Resistant Tuberculosis: A Cross-sectional Study from Uttarakhand State of North India

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ABSTRACT

Introduction: In India, a significant proportion of TB patients prefer to seek care from the private health sector which is vast, heterogenous and largely unregulated. Optimal management of MDR-TB by the private health sector is therefore crucial for India's Revised National Tuberculosis Control Programme's (RNTCP) effort to control drug resistant TB. The present study was therefore undertaken to assess whether the MDR-TB management practices of allopathic private practitioners (PPs) are according to the RNTCP's guidelines.

Material and methods: A cross-sectional study on MDR-TB management practices of 71 PPs practising in urban areas of districts of Kumaon Division of Uttarakhand Province of India.

Results: Of 71 PPs, there were 85.9% non-chest specialists and 14.1% chest specialists. Only 26 (36.6%) PPs could correctly define MDR TB. Majority PP's (63.4%) referred their suspected MDR-TB patients to public sector. Only 26 (36.6%) PPs prescribed MDR-TB treatment. Most PPs (61.5%) prescribed two or less number of 2nd line anti-TB drugs. Analysis in terms of one or more aspect of treatment i.e. composition of drug regimen, duration of treatment and drug dosages prescribed showed that none of the PPs, not even the chest specialists could write the RNTCP recommended MDR-TB treatment.

Conclusions: Management of MDR-TB in private health sector is largely sub-optimal.

Keywords: TB; MDR-TB; RNTCP; PPs

available from India and other parts of the world.⁹⁻¹⁴ Further, no document is available on the MDR-TB management practices of allopathic private practitioners (PPs) in Uttarakhand Province of North India. To fill this gap, this study was carried out among PPs practicing in urban areas of Kumaon Division of Uttarakhand to assess their knowledge and practices regarding management of MDR-TB. The results and recommendations of this study would help in designing interventions to optimize MDR-TB management practices of PPs which is crucial to achieve successful MDR-TB control in India.

MATERIAL AND METHODS

The study was intended to seek information on whether the MDR-TB management practices of PPs practicing in Uttarakhand state of North India are in line with the RNTCP recommended standards. This aim was achieved by analyzing the response of PPs to following questions- a) what is MDR-TB? and b) please write a prescription to a 50 kg weight MDR-TB patient.

Study design and setting

An observational cross-sectional study conducted from October 2013 to November 2014 among PPs practicing in urban areas of five of the total six districts of Kumaon Division of Uttarakhand Province of North India.

Study population

As per the information available from the State Register of Indian Medical Association (IMA) Uttarakhand, there were about 700 allopathic medical practitioners (private + public) practicing in Kumaon division of Uttarakhand, of which 500 were PPs among whom the study population was selected. Due ethical clearance was taken from the Institute Ethical Committee of Government Medical College Haldwani, Nainital, India.

INTRODUCTION

According to the World Health organization (WHO) Global Tuberculosis (TB) report for the year 2015, India has the highest burden of TB and multi drug resistant (MDR) TB with an estimated 1.3 lakh incident MDR TB patients emerging annually. The WHO recommended Revised National TB Control Programme (RNTCP) of India began diagnostic and treatment services for MDR TB in year 2007 and achieved nationwide coverage in 2013 with 126136 patients put on MDR TB till 2016 under its Programmatic Management of Drug Resistant TB (PMDT) strategy.¹

Though RNTCP delivers free of cost TB diagnostic and treatment services in India, 60-88% of Indian TB patients prefer to seek care from the private health sector² which is vast, heterogenous and largely unregulated. So far, many audits had reported that management practices in private health sector of India were sub-optimal.³⁻⁸ However, most such audits were primarily focused on private management of drug susceptible TB. On the subject as to how MDR-TB is managed in private health sector, only scant literature is

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Operational definitions¹⁵

The following RNTCP India guideline for diagnosis and treatment of MDR-TB which was applicable at the time of inception of this study was taken as standard for assessment of PPs' knowledge and practice about MDR-TB:

Definition of MDR-TB	M. tuberculosis resistant to isoniazid and rifampicin with or without resistance to other drug.								
Recommended drug regimen for MDR-TB	Intensive phase (6-9 months)					Continuation phase (18 months)			
	Km LvX Eto Cs Z E					LvX Eto Cs E			
Recommended drug dosages for 46-70 kg body weight MDR-TB patient	Km	Lvx	Eto	Cs	Z	E	Cm	PAS	Mfx
	750 mg	1000 mg	750 mg	750 mg	1500 mg	1200 mg	1000 mg	12 gm	400 mg
Km – Kanamycin, LvX – Levofloxacin, Eto – Ethionamide, Cs – Cycloserine, Z – Pyrazinamide, E – Ethambutol. Reserve/substitute drugs: Cm – Capreomycin, PAS – Para-amino salicylic Acid, Mfx - Moxifloxacin									

Sample size calculation

As no reliable information was available about the MDR-TB management practices of PPs in the study region, it was assumed that 50% of the PPs would be aware of management of MDR-TB under RNTCP. We used the formula $(1.96)^2 pq / d^2$ at 95% confidence interval with $d = 10\%$ desired level of precision for calculation of sample size. With this, the sample size was derived to be 96. As the sample size exceeded 5% of the source population, the final sample size came out to be 80 by using the correction formula of $nf = ni / (1 + ni/N)$ where nf = corrected sample size, ni = uncorrected sample size, and N = total number of all the source population.¹⁶

Sampling technique and study sample

The principal investigator (RGN) of this study who had been working in the region as tertiary care academician in the field of TB and respiratory diseases for more than a decade had frequent academic engagements with PPs in the region, and hence was well aware of the PPs who routinely catered large loads of patients in their clinical practice. The investigator line listed such PPs for purposive sampling and administered a semi-structured questionnaire during different continued medical education (CME) sessions. Some PPs, who could not be contacted during the CME sessions, were approached at their clinics. Due consent was taken from the PPs after explaining them the purpose of the study, assuring confidentiality and anonymity. After exclusions, a total of 71 PPs formed the study sample for final analysis (Fig.1).

STATISTICAL ANALYSIS

Data was entered in MS excel and descriptive analysis was done using numbers and percentages. Fisher's exact test was used for assessment of statistical significance of difference between proportions using software STATCALC of EPIINFO version 7.2.0.1. A P -value ≤ 0.05 was considered as statistically significant.

RESULTS

A total of 71 PPs were included in the study for assessment of their knowledge and practices related to MDR-TB. Table-1 shows that majority (85.9%) PPs were non-chest specialists, and 14.1% were chest specialists. The average duration of practice of PPs was 17.5 years with a range from

6 months to 50 years, and 36.6% had more than 20 years of practice. About two-third PPs were seeing less than 10 TB patients in a month.

Table 2 shows PPs knowledge and practice regarding MDR TB. Only 26 (36.6%) PPs could correctly define MDR TB.

Variables	Number (n=71)	Percent (%)
Professional qualification		
Chest specialists	10	14.1
Non- chest specialists	61	85.9
Place of practice		
Nainital	26	36.6
Udham Singh Nagar	32	45.1
Almora	09	12.7
Pithoragarh	03	04.2
Champawat	01	01.4
Duration of practice (years)		
0 – 5	16	22.5
6 – 10	13	18.3
11 – 20	16	22.5
>20	26	36.6
Number of TB patients seen every months		
<10	46	64.8
11– 30	15	21.1
>30	6	08.5
No response	4	05.6

Table-1: Demographic and practice profile of PPs

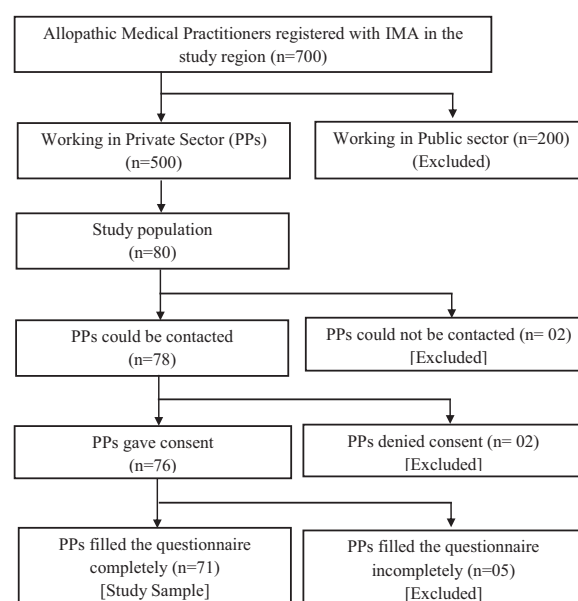


Figure-1: Study sample selection

Could define MDR-TB correctly	Practice	Chest specialists (n=10) N (%)	Non-chest specialists (n=61) N (%)	Total (n=71) N (%)	P value*
Yes	Referred to public sector	01 (10.0)	11 (18.0)	12 (16.9)	1.000
	Prescribed treatment	08 (80.0)	06 (09.9)	14 (19.7)	0.000
	Total	09 (90.0)	17 (27.9)	26 (36.6)	0.0003
No	Referred to public sector	00	33 (54.1)	33 (46.5)	0.001
	Prescribed treatment	01 (10.0)	11 (18.0)	12 (16.9)	1.000
	Total	01 (10.0)	44 (72.1)	45 (63.4)	--

*Fisher's Exact test; #Multiple responses

Table-2: Knowledge and practice of PPs regarding MDR-TB

Drugs	Chest specialists (n=09) N (%)	Non-chest specialists (n=17) N (%)	Total (n=26) N (%)	P Value*
Name of Drugs #				
Ethionamide	07 (77.7)	07 (41.2)	14 (53.8)	--
Levofloxacin	07 (77.7)	07 (41.2)	14 (53.8)	
Kanamycin	05 (55.5)	06 (35.3)	11 (42.3)	
Streptomycin	02 (22.2)	07 (41.2)	09 (34.6)	
Isoniazid	01 (11.1)	08 (47.1)	09 (34.6)	
Rifampicin	00	09 (52.9)	09 (34.6)	
Cycloserine	05 (55.5)	02 (11.7)	07 (26.9)	
PAS	01 (11.1)	03 (17.6)	04 (15.4)	
Ofloxacin	01 (11.1)	03 (17.6)	04 (15.4)	
Rifabutin	02 (22.2)	00	02 (07.7)	
Amikacin	01 (11.1)	00	01 (03.9)	
Moxifloxacin	01 (11.1)	00	01 (03.9)	
Protionamide	01 (11.1)	00	01 (03.9)	
Terizidone	01 (11.1)	00	01 (03.9)	
Number of second line drugs in the prescription				
0 – 2	02 (22.2)	14 (82.3)	16 (61.5)	0.008
3 – 4	07 (77.8)	03 (17.7)	10 (38.5)	

* Fisher's Exact test; #Multiple responses

Table-3: Drugs prescribed by the PPs for MDR-TB treatment

Deviation from RNTCP recommendation	Chest specialists (n=09) N (%)	Non-chest specialists (n=17) N (%)	Total (n=26) N (%)	P value*
Duration of treatment				
Over duration	00	00	00	--
Under duration	03 (33.3)	08 (47.1)	11 (42.3)	0.68
Duration not mentioned	03 (33.3)	08 (47.1)	11 (42.3)	0.68
Drug dosages#				
Over dosages(one or more drugs)	02 (22.2)	02 (11.7)	04 (15.4)	0.59
Under dosages (one or more drugs)	06 (66.6)	09 (52.9)	15 (57.7)	0.68
Dosages not mentioned (one or more drugs)	04 (44.4)	08 (47.1)	12 (46.1)	1.00
Composition of treatment regimen				
Conforming to RNTCP recommendation	03 (33.3)	00	03 (11.5)	0.03
Not conforming to RNTCP recommendation	06 (66.7)	17 (100)	23 (88.5)	
Overall incorrect treatment in terms of one or more i.e. regimen, duration or dosage	09 (100)	17 (100)	26 (100)	--

*Fisher's Exact test; #Multiple responses

Table-4: Magnitude of deviation of treatment

Significantly higher number of chest specialists compared to non-chest specialists (90% vs. 28%, P = 0.0003) correctly defined MDR-TB. Of the 71 PPs, majority (63.4%) referred their MDR-TB patients to public sector for further

management and the remaining 26 (36.6%) PPs which includes 12 (16.9%) PPs who could not correctly define MDR-TB, prescribed MDR-TB treatment.

In Table 3 and 4, summarizes analysis of knowledge and practice of 26 PPs who prescribed MDR-TB treatment. Table 3 mentions anti-TB drugs used by PPs. About one-third prescribers used first line anti-TB drugs viz streptomycin, Isoniazid and Rifampicin to their MDR-TB patients. Almost half the non-chest specialists prescribed Isoniazid and Rifampicin whereas among chest specialists 11.1% prescribed Isoniazid but none prescribed Rifampicin. The most common 2nd line anti-TB drugs prescribed were Ethionamide (53.8%), Levofloxacin (53.8%), Kanamycin (42.3%), Cycloserine (26.9%), Ofloxacin (15.4%) and PAS (15.4%). The other 2nd line drugs which were prescribed exclusively by chest specialists were Moxifloxacin (3.9%), Amikacin (3.9%), Rifabutin (7.7%), Protionamide (3.9%) and Terizidone (3.9%). Overall, majority prescribers (61.5%) used two or less number of 2nd line drugs. While majority of chest specialists used three to four 2nd line drugs, a significantly lower number of non-chest specialists did the same (77.8% vs. 17.7%, $P = 0.008$)

Table 4 shows magnitude of deviation of prescribers' MDR-TB treatment practice from RNTCP recommendations with regard to duration of treatment, drug dosages and composition of regimen. The overall duration of treatment prescribed ranged from 6 to 27 months. Under duration treatment was prescribed by 11 (42.3%) prescribers. Over-dosages and under dosages of one or more of drugs were prescribed respectively by 15.4% and 57.7% prescribers. Only 3 prescribers (11.1%), all of them chest specialists, could prescribe regimen conforming to RNTCP. However, on combining all deviations in terms of composition of regimen, duration of treatment and dosages of drugs, it was found that all the 26 (100%) prescribers of MDR-TB treatment irrespective of their speciality prescribed incorrect treatment.

DISCUSSION

Though RNTCP services are universally accessible throughout the country, private health sector is the dominant TB care provider to Indian TB patients. In year 2006, out of the total \$ 94 million first line anti-TB drug market, in India drugs worth \$70 million were purchased by private sector alone.¹⁷ In the same year, of the total \$ 8.4 million worth second line anti-TB drugs sold in India nearly all were purchased by the private sector.¹⁸ These market surveys indicate that the private health sector in India manages a significantly higher proportion of drug sensitive TB and MDR-TB patients. As TB management in private sector had been reported to be sub-optimal, and as India has the highest burden of MDR-TB in the world, the private health sector may potentially disrupt RNTCP's effort to control drug resistant TB in India. The present study highlights the status of MDR-TB management practices prevalent in private health sector.

Our study documents that overall only 26 (36.6%) PPs could correctly define MDR-TB. A significantly higher number of

chest specialists compared to the non-chest specialists (90% Vs 28%; $p=0.0003$) defined MDR-TB correctly. Basu M et al. from West Bengal had reported that only 28.3% doctors could rightly define MDR-TB.¹⁹ Vandan N et al. from Lucknow, India however had reported better understanding of MDR-TB among PPs.⁹

An interesting finding in this study was that of 71 PPs, 63.4% were not managing their MDR-TB patients themselves, instead they referred them to public sector for management. This action of the PPs is in contrast to their behavior for drug sensitive TB, which was evident in an earlier study conducted among the same study participants at the same time and setting where majority (95.8%) of PPs didn't refer their drug sensitive TB patients to the public health sector.²⁰ Possible reasons for this differential referral behavior of PPs might be – One, fear of contracting infection from MDR-TB patients; Two, feeling of inadequacy of knowledge about management of MDR-TB; Three, unavailability of MDR-TB drug blister pack formulations in the market which otherwise could have helped them prescribing readymade regimen for different weight- band patients. It is also interesting to note that 16.9% PPs, who could not even define MDR-TB correctly, prescribed treatment for MDR-TB.

It is evident in this study that while the RNTCP guideline 2012 for MDR-TB recommended use of at least four second line anti-TB drugs (Km Lvx Eto Cs) along with two first line drugs (Z, E) during intensive phase of the treatment, of the 26 PPs majority (61.5%) used two or less number of second line anti-TB drugs in the regimen. Further, it was observed that a significantly higher number of non-chest specialists prescribed such inadequate regimens compared to chest specialists (82.3% Vs 22.2%; $p=0.008$). This inadequacy of knowledge of PPs has serious public health implications of creating extensively drug resistant TB (XDR-TB).

It was observed in this study that of 26 prescribers, 42.3% prescribed the treatment for under duration and 57.7% used drugs in under-dosage. There was no significant difference between chest specialists and non- chest specialists with regard to prescription of under duration of treatment (33.3% Vs 47.1%; $p=0.68$) and use of under-dosage of drugs (66.6% Vs 52.9%; $p=0.68$). This highlights that chest specialists fared no better than the non-chest specialists.

This study found that among 26 PPs who prescribed MDR-TB regimen, only 11.5%, all of them chest specialists could prescribe a regimen conforming in composition to the RNTCP recommended MDR-TB regimen. However, it is perplexing to note that though the chest specialists were expected to manage MDR-TB as per RNTCP recommendations, only one-third (33.3%) chest specialists could correctly write the recommended composition of drug regimen. This highlights the gap in teaching and training TB to chest specialists as per RNTCP guidelines during their post graduate study period.

It is interesting to note that when data were analyzed for overall prescription error in terms of one or more aspect of treatment i.e. composition of drug regimen, duration of treatment and drug dosages prescribed, none of the PPs, not even the chest specialists could write the RNTCP recommended MDR-TB

treatment. Udwardia et al. from Mumbai had reported that only 6 (5.6%) of their 106 study respondents could write MDR-TB treatment prescription with a minimum of three new second line drugs in right dose for a right duration.⁶ In India, which is home to largest burden of MDR-TB in the world, this observation is worrisome.

An important limitation of this study is that it was done using purposive sampling. However, the sample was comprised of PPs who were academically active practitioners of repute in the study setting, and were hence expected to be better informed about MDR-TB. We could not include 11% of desired study sample. As this is an interview based study, this study was test of knowledge of the PPs and not their actual practice.

CONCLUSION

To conclude, it is evident that management of MDR-TB in India's private health sector is largely sub-optimal. This study highlights the need to plan strategies to minimize mismanagement of MDR-TB in the private health sector. This may be achieved by introducing following interventions:

1. As most TB patients prefer to seek care from the private sector, creation of separate manpower structure under RNTCP uniquely dedicated to train PPs in RNTCP and help them managing their TB patients is recommended.
2. Up scaling visibility of RNTCP among general public and PPs by maximally utilizing print and electronic media.
3. Provision of ensured delivery of at least quarterly TB news letter, medical update and continuing medical education to all PPs.
4. Making public sector run MDR-TB diagnostic and follow up laboratory services accessible to PPs.
5. Ensuring availability of weight band-wise blister packs of MDR-TB drugs to minimize prescription errors with respect to composition of regimen and drug dosages.
6. Provision of compulsory teaching and training in RNTCP to all kinds of medical practitioners irrespective of their speciality.

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