



TO STUDY THE CLINIC-RADIOLOGICAL OUTCOME OF CONFIRMED XDR PULMONARY TUBERCULOSIS

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**ABSTRACT**

**Background-** To study the clinic-radiological outcome of confirmed XDR pulmonary tuberculosis

**Methods-** This study is done to document the distribution of patients, sputum conversion, six months outcome and their pharmacovigilance and treatment registered at DR TB CENTRE Vadodara site.

**Results-** In our study out of 66 patients 14 (21%) patients died during study period of 6 months and 52 (78%) remained alive. In 52 patients 24 (46%) patients put on weight in 6 months and 14 (27%) remained static and 14 (27%)

**Conclusion-** XDR TB is a threat to the global tuberculosis control strategies. XDR TB treatment with second line AKT is of longer duration, with higher incidence of Adverse reaction thus increasing the morbidity and cost, making compliance more difficult.

**KEYWORDS :** XDR, TB, MDR

**INTRODUCTION**

“MDR-TB” An MDR-TB suspect who is sputum culture positive and whose TB is due to Mycobacterium tuberculosis that are resistant in-vitro to at least isoniazid and Rifampicin (the culture and DST result being from an RNTCP accredited laboratory).<sup>1</sup>

“XDR-TB” is defined as infection with Mycobacterium tuberculosis strains that has developed resistance to at least rifampicin and isoniazid (resistance to these first line anti-TB drugs defines Multi-drug-resistant tuberculosis, or MDR-TB), as well as to any member of the quinolone family and at least one of the following second line anti-tb injectable drugs: kanamycin, capreomycin, or amikacin.<sup>2</sup>

There are no such systematic studies of laboratory confirmed XDR pulmonary tuberculosis carried out till now. Keeping his background in mind the present study was conducted with aims and objectives of analysis of clinical and radiological profile, efficacy and adverse drug reactions to standardized catv regimen.

**MATERIAL & METHODS**

The present study was carried out in a teaching hospital during the year 2014-2015 at the DOTS PLUS SITE OF PULMONARY MEDICINE DEPARTMENT OF MEDICAL COLLEGE BARODA & S.S.G. HOSPITAL VADODARA. All the patients studied were the confirmed cases of XDR Pulmonary TB who were enrolled in drug resistant TB Register on CAT-V Regimen after pretreatment evaluation during the calendar year 2014.

The study was undertaken after clearance from scientific review committee and institutional ethical committee for human research (IEHR) GOVT MEDICAL COLLEGE VADODARA.

**PURPOSE AND UNIQUENESS OF STUDY:**

After giving treatment XDR patients under RNTCP at present there is irregular follow up documented in these patients. Treatment outcome is given only on following sputum culture results but we would like to study clinical status and radiological status and adverse drug reactions in relation with intrinsic outcome of 6 months of starting therapy. Until now studies of XDR TB patients were done on individualized regimen but no study has been done on standardized AKT cat-V regimen under PMDT among these (Jan 14 - Sept 14) patients registered at drug resistant TB site Vadodara. Under PMDT services cat-V regimen drugs are made available for last 2-3 years only factors related to poor adherence to treatment also will be studied. So we can compare programmatic and clinical situation also.

**INCLUSION CRITERIA:**

- Patients who are newly diagnosed XDR-Pulmonary Tuberculosis whose Sputum Culture and DST results reports format RNTCP accredited laboratory, IRL Ahmedabad are found resistance to KANAMYCIN / OFLOXACIN at 6 months follow up sputum after starting MDR TB CATIV in MDR TB patients.
- Patients who are registered and initiated treatment (DURING JANUARY 2014 TO SEPTEMBER 2014) at a tDR TB centre, Medical college & S.S.G. Hospital, Vadodara
- Patients of XDR-TB who are above 15 years of age are included in our study.

**EXCLUSION CRITERIA:**

1. XDR-Pulmonary TB Patients who are below 15 years.
2. Extra pulmonary XDR TB Patients.

**STUDY DESIGN**

“SIX MONTHS OUTCOME OF XDR PULMONARY TUBERCULOSIS PATIENTS., REGISTERED AT DRUG RESISTANT TB CENTER S.S.G. HOSPITAL VADODARA” It is a Prospective & Retrospective observational study.

**STUDY PERIOD:**

Study period for these patients after approval from scientific and ethical committee from (JANUARY 2014 to SEPTEMBER 2014). Till JUNE 2015.

**DATA ANALYSIS:**

The form was checked for error and corrected on the same day of data collection. The data so collected had been compiled and later on entered in the excels 2007 worksheet. The analysis was done using Epi Info statistical software.

**OBSERVATION**

**TABLE-1**

**AGE AND SEX WISE DISTRIBUTION OF PATIENTS OF XDR PULMONARY TUBERCULOSIS (N=66)**

AGE GROUP	NUMBER OF PATIENTS				TOTAL (N=66)	
	MALE (n=51)	Percentage	FEMALE (n=15)			
10-20	0	0.00 %	2	3.03 %	2	3.03 %
21-30	9	13.64 %	4	6.06 %	13	19.70 %
31-40	20	30.30 %	7	10.61 %	27	40.90 %
41-50	19	28.79 %	2	3.03 %	21	31.82 %
51-60	3	4.55 %	0	0.00 %	3	4.55 %
>60	0	0.00 %	0	0.00 %	0	0.00 %
<b>TOTAL</b>	<b>51</b>	<b>77.27 %</b>	<b>15</b>	<b>22.73 %</b>	<b>66</b>	<b>100 %</b>

Male to female ratio is 3.6 : 1. So male were more commonly

affected by XDR pulmonary tuberculosis. Maximum patients were in the age group of 31-40 years in case of male (30.30%) and female (10.61%). Mean age of the patients is 39.4 years youngest one 17 yrs and oldest patient was 50 years old .

**Table 2**  
**RADIOLOGICAL INVOLVEMENT AS PER SITE AT THE TIME OF DIAGNOSIS IN XDR TB PATIENTS (N = 66)**

UNILATERAL		BILATERAL	TOTAL
RT	LT		
0	4(6%)	62(94%)	66(100%)

The above table shows that chest X ray examination was done in 66 patient at pre treatment evaluation amongst the m total 62 patients were having Bilateral lesions in the X-rays. In both genders bilateral lesion was more common. unilateral lesion

**Table 4. Six month outcome of patients.**

SIX MONTHS OUTCOME								
CULTURE OUTCOME (n=40)				RADIOLOGICAL OUTCOME (n=35)				
			Positive	Negative			Positive	Negative
1	Age	<45yrs	13	15	Age	<45yrs	25	1
		>45yrs	9	3		>45yrs	7	2
2	Sex	male	19	15	Sex	male	25	3
		female	3	3		female	7	0
3	wt in kg	<45kg	16	16	wt in kg	<45kg	24	2
		>45kg	6	2		>45kg	8	1
4	BMI	<18kg/M2	14	15	BMI	<18kg	24	1
		>18kg/M2	8	3		>18kg	8	2
5	HB	<10	10	9	HB	<10	13	2
		>10	12	9		>10	19	1
6	comorbidities	present	4	2	comorbidities	present	4	2
		absent	18	16		absent	28	1
7	cavitatory lesion	present	14	13	cavitatory lesion	present	25	2
		absent	8	5		absent	7	1

**DISCUSSION**

The study of XDR TB patients registered in drug resistant TB centre vadodara was done under PMDT programme in an optimum resource setting. Our treatment regimen was provided as per PMDT guidelines. Most of the Patient were admitted at the time of pretreatment evaluation and AKT CAT V regimen was provided with daily dose of injection capreomycin and other drugs. Patients having adverse reactions were also admitted and pharmaco-vigilance was done. Dose was adjusted/ replaced according to PMDT guidelines.

INTENSIVE PHASE was started for six months for extremely drug resistant TB and follow up cultures were sent to IRL ahmedabad and treatment was given from local centre by DOTS provider after discharge from our centre.

Many XDR TB treatment programmes in resource poor countries are likely to encounter difficulties in attaining such high levels of supervision.

We have compared our study with Dr Kumar utsav etal .<sup>4</sup>from Ahmedabad civil hospital.(case series of 83XDR TB patients in trim analysis)

We have compared our study with Dr. Mani tiwari etal .<sup>5</sup> from Surat civil hospital.(adversedrug reactions observed in XDR patients in 6 months of initiation of catv treatment)

According to the study done by Kumar Utsav <sup>etal</sup> at ahmedabad, culture of 11 patients were +ve at the end of 12 months. 22 patients had -ve. Out of which 5 patients culture was reverted to +ve. There were 22 patients whose culture was -ve at 12 months Out of Which 19 patients had culture conversion. Culture report of 20 patients was not available. Out of 83,30 patients died.

was in only 4 patients

**Table-3**  
**RADIOLOGICAL LESION IN XDR TB PATIENTS AT THE INITIATION OF TREATMENT (CHEST XRAY) (N=66)**

LESION	MALE	FEMALE	TOTAL
CAVITATORY	34	10	44
NONCAVITATORY	17	5	22
TOTAL	51	15	66

The above table shows that chest X ray examination was done in 66 patient amongst them total 44 patients were having cavitatory lesions in the X rays. Amongst them male were 34 and female were 10 In both the gender cavitatory lesion were more common.

**Table 4. Six month outcome of patients.**

SIX MONTHS OUTCOME								
CULTURE OUTCOME (n=40)				RADIOLOGICAL OUTCOME (n=35)				
			Positive	Negative			Positive	Negative
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		>45yrs	9	3		>45yrs	7	2
2	Sex	male	19	15	Sex	male	25	3
		female	3	3		female	7	0
3	wt in kg	<45kg	16	16	wt in kg	<45kg	24	2
		>45kg	6	2		>45kg	8	1
4	BMI	<18kg/M2	14	15	BMI	<18kg	24	1
		>18kg/M2	8	3		>18kg	8	2
5	HB	<10	10	9	HB	<10	13	2
		>10	12	9		>10	19	1
6	comorbidities	present	4	2	comorbidities	present	4	2
		absent	18	16		absent	28	1
7	cavitatory lesion	present	14	13	cavitatory lesion	present	25	2
		absent	8	5		absent	7	1

Initiative Barcelona, Spain 2014 was reported that Out of 1269 patients studied ,421 were defaulter, 438 died & 284 patients completed treatment.

According to the Present study, culture of 11 patients were +ve at the end of 6 months. 18 patients had -ve. Out of which 5 patients culture was reverted to +ve. 11 patients had culture conversion. Culture report of 6 patients was not available. Out of 66, 14 patients died.

**CONCLUSION**

XDR TB is a threat to the global tuberculosis control strategies. XDR TB treatment with second line AKT is of longer duration, with higher incidence of Adverse reaction thus increasing the morbidity and cost, making compliance more difficult.

**REFERENCES**

1. Global tuberculosis control. WHO report 2001. Geneva, World Health Organization, 2001 (document WHO/CDS/TB/2001.287).
2. Centers for Disease Control and Prevention (CDC) Emergence of *Mycobacterium tuberculosis* with extensive resistance to second-line drugs—worldwide, 2000–2004. MMWR Morb Mortal Wkly Rep. 2006;55:301–5
3. World Health Organization. Emergency update 2008. Geneva: World Health Organization; 2008. Guidelines for the programmatic management of drug-resistant tuberculosis.
4. www.ers.edu.com. case series of 83 Xdr TB patients in Gujarat in trim analysis is by Dr. kumar utsav <sup>et al</sup> civil hospital ahmedabad.
5. Dr. mani tiwari <sup>et al</sup> civil hospital Surat. (adverse drug reactions observed in XDR patients in 6 months of initiation of cat v treatment in Tertiary care centre of southern Gujarat, India presented in NESCON 15)