

## NEED FOR ENHANCED IEC ACTIVITIES

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It has become apparent that without sustained social mobilization by conducting regular and effective Information, Education and Communication (IEC) activities, achieving global targets of 70% smear positive case detection rate and 85% successful treatment of such cases is not possible. To attain these goals, a forum of NGOs working in different regions of the world should share their experiences and success stories<sup>1,2</sup>.

In India the government has clearly specified areas of NGOs' involvement in the Revised National Tuberculosis Control Programme (RNTCP). They have developed five different types of schemes under which NGOs can take part in successful implementation. And their active participation in TB control programme. Based on RNTCP's experience with NGOs, the guidelines that have been developed provide different schemes of financial and/or commodity assistance to the NGOs interested in collaborating with RNTCP. Presently more than 2000 NGOs are providing services as per the RNTCP guidelines. The bigger NGOs like Indian Medical Association (IMA) and Mission Hospital Associations are collaborating with RNTCP at national and state levels, in addition to the local collaborations. The websites in reference to NGOs are [www.prasar.org](http://www.prasar.org) and [www.sardindia.org](http://www.sardindia.org).

The Central TB Division has started four Urban DOT projects in Hyderabad, Indore, Mumbai and Varanasi which have large numbers of slum dwellers and migrant population. The four project sites will establish model "Urban TB Control Projects" by improving the quality and reach of RNTCP to special groups like slum dwellers and migrants, through more "patient-friendly" treatment observation, involvement of private and NGO sectors and IEC. Thus, they will increase the reach of RNTCP by making DOTS more accessible and acceptable among disadvantaged urban poor population<sup>3</sup>.

Here, we are citing two such areas of health education and community outreach. The German Leprosy and TB Relief Association (GLRA) and Swiss Emmaus Leprosy Relief Work (ALES – India), already experienced as working with district level technical teams in leprosy eradication working in Kerala and Rajasthan, took up work in TB control. Through cost-effective interventions in their project areas, they are achieving a case detection rate of 70% and a cure rate of over 85%. Their TB control network now includes a number of education and community outreach programmes, DOTS centres, Microscopy and Treatment Centres and TB units. In Kerala and Rajasthan, GLRA partners with RNTCP to provide technical support in IEC and build up the capacity of local NGOs, field workers and other stake-holders. High cure rates achieved in these projects show that NGOs can effectively contribute in controlling tuberculosis<sup>4</sup>.

This issue contains two articles highlighting the importance of social mobilisation in TB control programme and the need for enhanced IEC activities in the success of TB control programme.

The article in this issue from the rural areas of Rajasthan highlights the lack of knowledge, attitude and practice among sand stone quarry workers, working in the deserts of Rajasthan<sup>5</sup>. Among the 371 workers interviewed who have overall literacy rate of 25.7%, it was surprising to note that only

1.6% knew that tuberculosis is caused by the germs and only 6.9% knew about the need of treatment for 6-8 months' duration and 0.8% knew about the preventive role of BCG. On the other hand, 72.6% respondents had the myth that TB patients should be isolated from the family and 80.6% had misconceptions that food sharing should be avoided with these patients. This substantiates our view that there is still an appalling ignorance and superstition about the disease, its spread, causation, etc. There is a dire need for creating awareness, so as to remove myths about tuberculosis in such groups of people in the community.

On social mobilization, there are different ways which are being employed by various agencies on different occasions. The second related article in this issue is a study from rural community in south India<sup>6</sup>. It has highlighted and identified different communication channels for spreading awareness about the tuberculosis problem in the community. In this community-based study 38% of the people were illiterates. The main sources of communication, commonly identified, were television and wall posters. Another method of dissemination found to be very effective was the role of local associations in the villages as 50% of these already had such type of local bodies. If we motivate and convince these bodies, they can be very effective means of IEC activities in the local community.

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## PERFORMANCE OF A DOTS PROGRAMME: ADMINISTRATIVE AND TECHNICAL CHALLENGES - A FIELD REPORT FROM A DISTRICT IN SOUTH INDIA

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### Summary

**Background:** Performance of tuberculosis (TB) control programme depends on the functioning of health facilities (HFs). TB control programmes have been evaluated based on the programme indicators of conversion and cure. We have attempted to correlate the programme performance based on the availability of staff and their performance at the HF level.

**Objective:** To correlate the performance of HFs to programme indicators, conversion and cure of patients treated under DOTS, in a district of south India.

**Design:** Analysis of the data on new sputum smear-positive cases registered in 17 HFs during 1999-2003 was undertaken using TB register. The HFs with a low conversion or cure rates were identified and the reasons for the same were analysed. A scoring system was designed for the functioning of the HFs based on staff availability, supervision and review meetings which was correlated with programme performance. Univariate and multivariate analyses were performed.

**Results:** Of 1893 new smear-positive patients registered during the study period, conversion was 1582 (83.6%) with cure rate of 76.4% (1447 of 1893), 254 (13.4%) default, 94 (5.0%) failure and 85 (4.5%) death. The conversion rates increased from 76% in 1999 to 87% in 2003; a statistically significant trend ( $\chi^2 = 15.9$ ;  $P < 0.001$ ). Similarly, a significant increase in trend ( $\chi^2 = 4.0$ ;  $P < 0.05$ ) was observed in cure rates also (71 to 80%). The HFs were broadly classified into four groups namely; poor, fair, good and very good based on functioning scores. Correlation co-efficient was 0.77 between functioning of the HFs and conversion, and 0.76 between functioning and cure ( $P < 0.01$ ). Lack of regular review meetings was found to be independently associated with poor programme performance.

**Conclusion:** Availability of staff such as Medical Officer, Laboratory Technician, and regular supervisory visits and review meetings are essential for a well functioning of programme. There is significant impact on DOTS with good functioning of HFs. [Indian J Tuberc 2006; 53:123-134]

**Key words:** TB, conversion, cure, performance, DOTS.

## INTRODUCTION

Directly Observed Treatment-Short-course (DOTS) is the globally recommended standard of care for management of TB. Government of India has implemented the DOTS strategy in the Revised National Tuberculosis Programme (RNTCP) introduced in 1993<sup>1,2</sup> and expanded in a phased manner. And has covered more than one billion population by 2005. The DOTS strategy, with the objectives of curing at least 85% new smear-positive cases and detecting a minimum of 70% of these cases, clearly emphasizes the importance of its various components like case detection, directly

observed treatment, uninterrupted drug supply, monitoring of the progress, proper documentation and reporting. This strategy has been beneficial and successful in reducing the death rate and increasing the favourable treatment outcomes<sup>3</sup>. It reduces the chances of failure and relapse. And prevents emergence of multi-drug resistant TB (MDR-TB).

Under RNTCP, there is an additional supervisory unit for every 500,000 population (TB Unit: TU) headed by a Medical Officer TB control (MOTC). Adequate and uninterrupted monitoring activities such as follow-up by sputum examination at regular intervals and outcome evaluation is ensured

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by Senior Treatment Laboratory Supervisor (STLS) and Senior Tuberculosis Supervisor (STS), two key personnel performing supervision on a daily basis, assisted by other health workers in the TU. MOTC conducts supervisory visits at least seven days in a month and supervises the functioning of the HFs in the TU. At each HF, a Medical Officer (MO) is in-charge of programme implementation and monitoring by regular supervisory visits and review meetings. The ultimate aim of this programme is to cure the patients and cut the chain of transmission for the control of TB.

Government of Tamil Nadu implemented the DOTS programme in a semi-urban population in Tiruvallur district in 1999 and TB Research Centre monitored the programme in one TU intensively for a period of 5 years since its implementation. We have undertaken several operational studies on various key aspects of DOTS strategy with a view to improving the performance and documented valuable information. However, the administrative and technical challenges have not been addressed so far.

This paper describes the performance of the DOTS programme in different governmental HFs as measured by programme indicators. Even though, the conversion and cure rates are the outcome of many factors, we have attempted to correlate them with the performance of the HFs.

## MATERIAL AND METHODS

The study area is a semi-urban population of Tiruvallur district where the RNTCP was introduced in 1999. There are 17 governmental HFs catering to the health needs of an estimated population of 5,80,000 spread over 209 villages and nine urban clusters. Of these, seven offer microscopic facilities for diagnosis of TB. The study area has been divided into 5 blocks (these are five Panchayat Unions divided into five blocks for revenue and administrative purposes by the State Government), each block having 3-4 HFs. Subjects reporting voluntarily with cough of three weeks or more were investigated using sputum microscopy and those who were diagnosed were treated as per RNTCP guidelines<sup>4</sup>. The study subjects included all new smear positive TB patients

who were registered under RNTCP at one of the above HFs from May 1999 to December 2003. The standard definitions were used for disease classification and programme indicators like conversion and treatment outcomes<sup>5</sup>.

## Data collection

Data on the initial results of sputum, classification of disease, follow-up smear results and treatment outcome were collected from the TB register maintained by the TU. After obtaining permission from the concerned state authorities, a field supervisor visited all the 17 HFs and collected the following data: leave and transfer particulars of MO, Village Health Nurse/Health Inspector (VHN/HI), Laboratory Technician (LT) and Pharmacist; the number of supervisory visits to field, number of review meetings held by verifying the relevant registers, holding health and other camps and occurrence of any social incidents like community clash or riots that might have affected the performance of HF activities during the period 1999-2003.

## Data analysis

All data were computerized, edited and corrected for missing information. The overall conversion and cure rates were estimated and compared over the period 1999-2003. We compared the functioning of the HFs in each block with the programme indicators namely, conversion and cure. These indicators were further looked into for each block and the HFs with a poor performance of DOTS in terms of conversion and cure rates were identified and the possible explanation for the same was explored, identified and discussed.

## Functional score

We designed a scoring system to evaluate the programme performance vis-à-vis the score for each HF year-wise. A score of '1' (otherwise '0') was given for each of the eleven parameters assessed as given below: Availability of (1) MO, (2) MOTC, (3) LT, (4) Pharmacist, (5) conducted review meeting, supervisory field visits by (6) MO, (7)

**Table 1:** Characteristics of TB patients registered under DOTS programme (between 1999–2003) in Tiruvallur district, south India

	Block					Total N 1893
	A n 429	B n 358	C n 546	D n 322	E n 238	
<b>Age in years</b>						
< 45	52.9	53.9	52.4	51.9	52.5	52.7
≥ 45	47.1	46.1	47.6	48.1	47.5	47.3
<b>Sex</b>						
Male	74.1	76.0	78.4	72.7	76.5	75.8
Female	25.9	24.0	21.6	27.3	23.5	24.2
<b>Literate</b>						
Yes	43.9	53.6	60.6	70.0	50.9	55.7
No	56.1	46.4	39.4	30.0	49.1	44.3
<b>Employed</b>						
Yes	70.6	75.8	59.0	66.4	64.7	66.9
No	29.4	24.2	41.0	33.6	35.3	33.1
<b>Smear at admission</b>						
2+, 3+	64.1	52.2	57.0	61.5	55.5	58.3
Scanty & 1+	35.9	47.8	43.0	38.5	44.5	41.7
<b>Conversion</b>						
Yes	80.4	86.9	83.7	80.7	87.8	83.6
No	19.6	13.1	16.3	19.3	12.2	16.4
<b>Cure</b>						
Yes	74.6	81.8	73.8	72.7	82.8	76.4
No	25.4	18.2	26.2	27.3	17.2	23.6

Note: The figures indicate proportion (%) to the total cases.

**Table 2:** Correlation between functional score for the HF and programme performance under DOTS programme in Tiruvallur district, south India

Year	Functional score								Trend $\chi^2$	
	Poor		Fair		Good		Very good		Conv.	Cure
	Conv. (%)	Cure (%)	Conv. (%)	Cure (%)	Conv. (%)	Cure (%)	Conv. (%)	Cure (%)		
1999	72	65	70	68	77	82	94	85	5.6	5.5
2000	64	64	85	77	84	83	90	86	P<0.05	P<0.05
2001	75	69	79	68	90	78	90	84	16.1	14.0
2002	83	79	87	77	86	76	93	85	P<0.001	P<0.001
2003	77	67	86	77	91	88	94	83	11.2	7.8
									P<0.001	P<0.05
									5.52	1.34
									P<0.05	NS
									13.9	9.0
									P<0.001	P<0.05

MOTC, (8) VHN/Hi (9) other state officials, (10) No occurrence of community clash and (11) no other governmental health speciality camps held. These scores were added for each HF year wise. All HFs were broadly classified into four groups namely; poor,

fair, good and very good based on percentiles (25, 50, 75, and above 75% respectively) of scores given. The overall conversion and cure rates of the HFs that included in each of these groups were calculated and compared. The functional score was then

**Table 3:** Risk factors for conversion and cure among new sputum smear positive TB patients

	<b>Total</b>	<b>Conv* (%)</b>	<b>Cure** (%)</b>
<b>MO</b>			
Available	69	41 (59.4) <sup>+</sup>	39(56.5) <sup>+</sup>
Not available	16	4	4
<b>VHN</b>			
Available	73	42(57.5) <sup>NS</sup>	40(54.8) <sup>NS</sup>
Not available	12	3	3
<b>LT</b>			
Available	55	39(70.9) <sup>#</sup>	33(60.0) <sup>+</sup>
Not available	30	6	10
<b>Pharmacist</b>			
Available	72	41(18.1) <sup>NS</sup>	39(54.2) <sup>NS</sup>
Not available	13	4	4
<b>Review meeting</b>			
Conducted	47	37(78.7) <sup>#</sup>	33(70.2) <sup>#</sup>
Not conducted	38	8	10
<b>MO</b>			
Visited	34	29(85.3) <sup>#</sup>	25(73.5) <sup>+</sup>
Not visited	51	16	18
<b>MOTC</b>			
Visited	36	27(75.0) <sup>+</sup>	25(69.4) <sup>‡</sup>
Not visited	49	18	18
<b>VHN</b>			
Visited	56	37(66.1) <sup>‡</sup>	34(60.7) <sup>+</sup>
Not visited	29	8	9
<b>Others</b>			
Visited	42	29(69.0) <sup>‡</sup>	28(66.7) <sup>‡</sup>
Not visited	43	16	15
<b>Community clash</b>			
No	83	44(53.0) <sup>ND</sup>	42(50.6) <sup>ND</sup>
Yes	2	1	1
<b>Health camps</b>			
Yes	53	33(62.3) <sup>+</sup>	32(60.4) <sup>+</sup>
No	32	12	11

\* ≥85% (median) \*\* ≥ 78% (median);<sup>+</sup> P <0.05; <sup>#</sup> P<0.01; <sup>‡</sup> P <0.001;

NS-Not significant; ND- Test of significance not done;

**Note:** In multivariate analysis, conducting review meetings was an independent risk factor associated with the higher conversion and cure rates. Availability of LT was an additional factor for a higher cure rate.

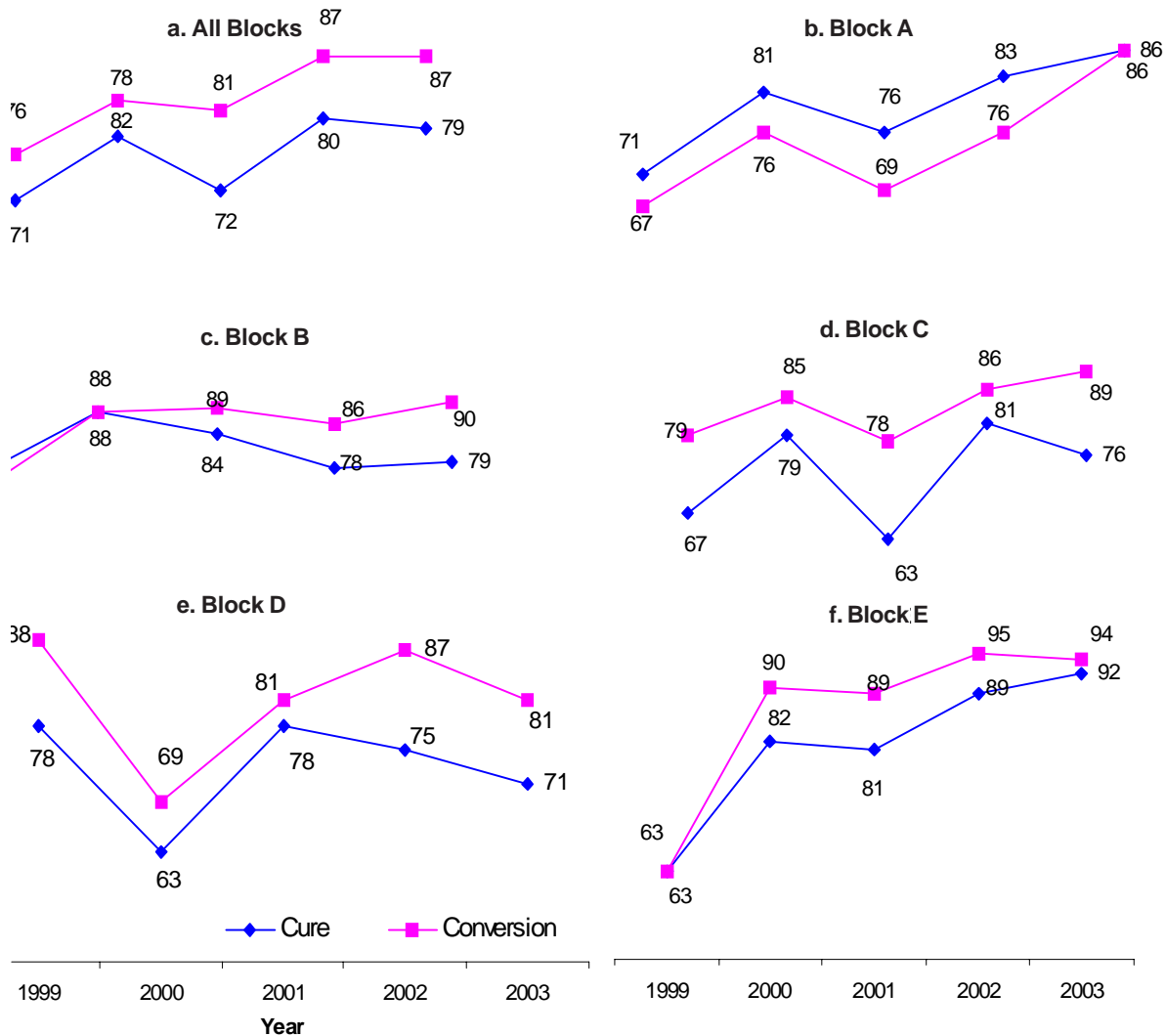
correlated with these indicators.

A univariate analysis was performed to identify potential factors among those patients with a high conversion and those with a low conversion taking the median value as the cut-off (similarly for cured cases also). The Chi-square test of significance was used to test the difference in proportion of converted cases among patients with and without factors (similarly for cured cases also). Logistic regression analysis was performed for those risk factors found significant in the univariate analysis. Trend chi-square was used to test the

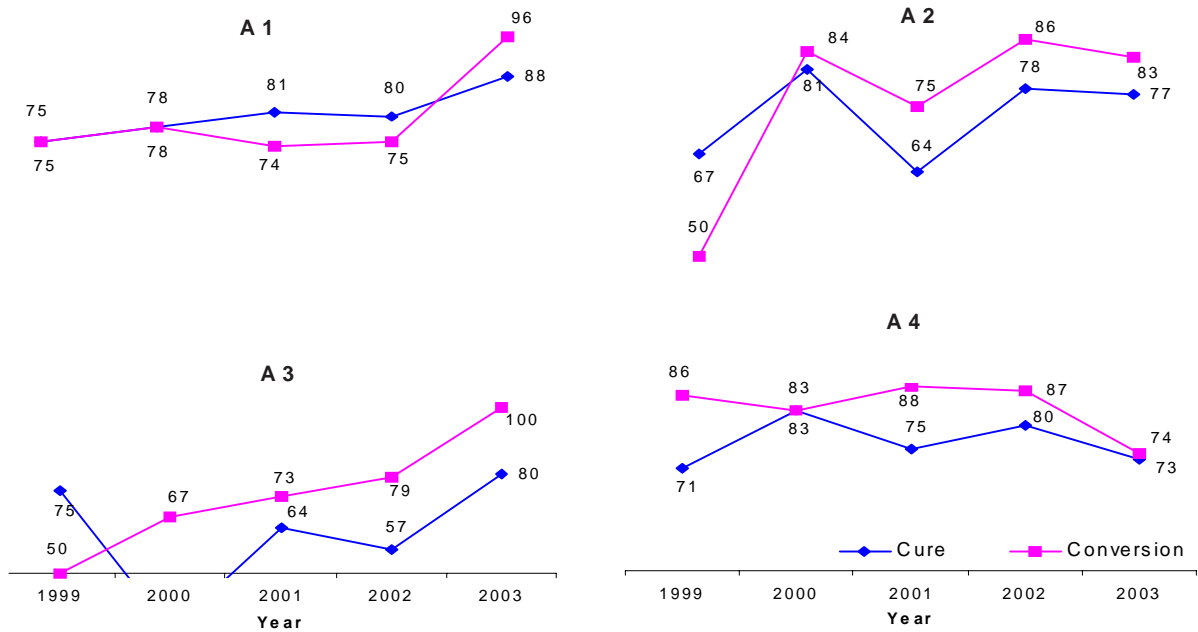
significance of trend of the performance over years. A P value of <0.05 was considered as statistically significant.

**RESULTS**

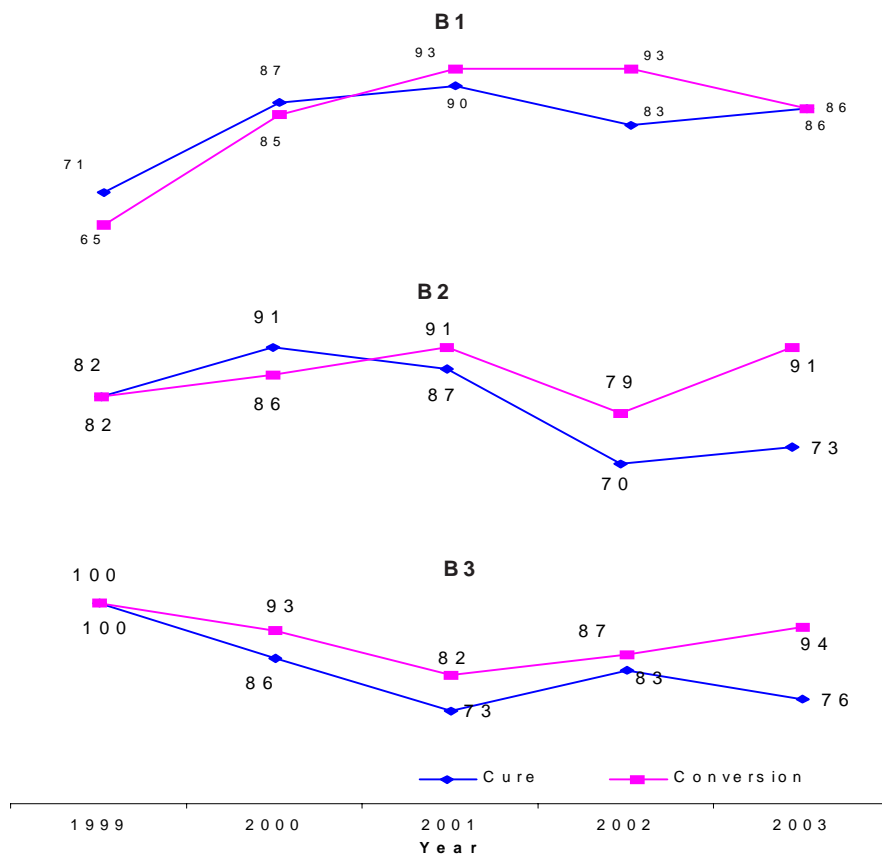
The demographic and other basic characteristics of all patents in the five blocks are given in Table 1. The age and sex compositions of the patients were found to be similar in all blocks. Fig 1a shows the conversion and cure rates of new smear positive cases in the TU from 1999 to 2003. The conversion rates increased from 76% in 1999



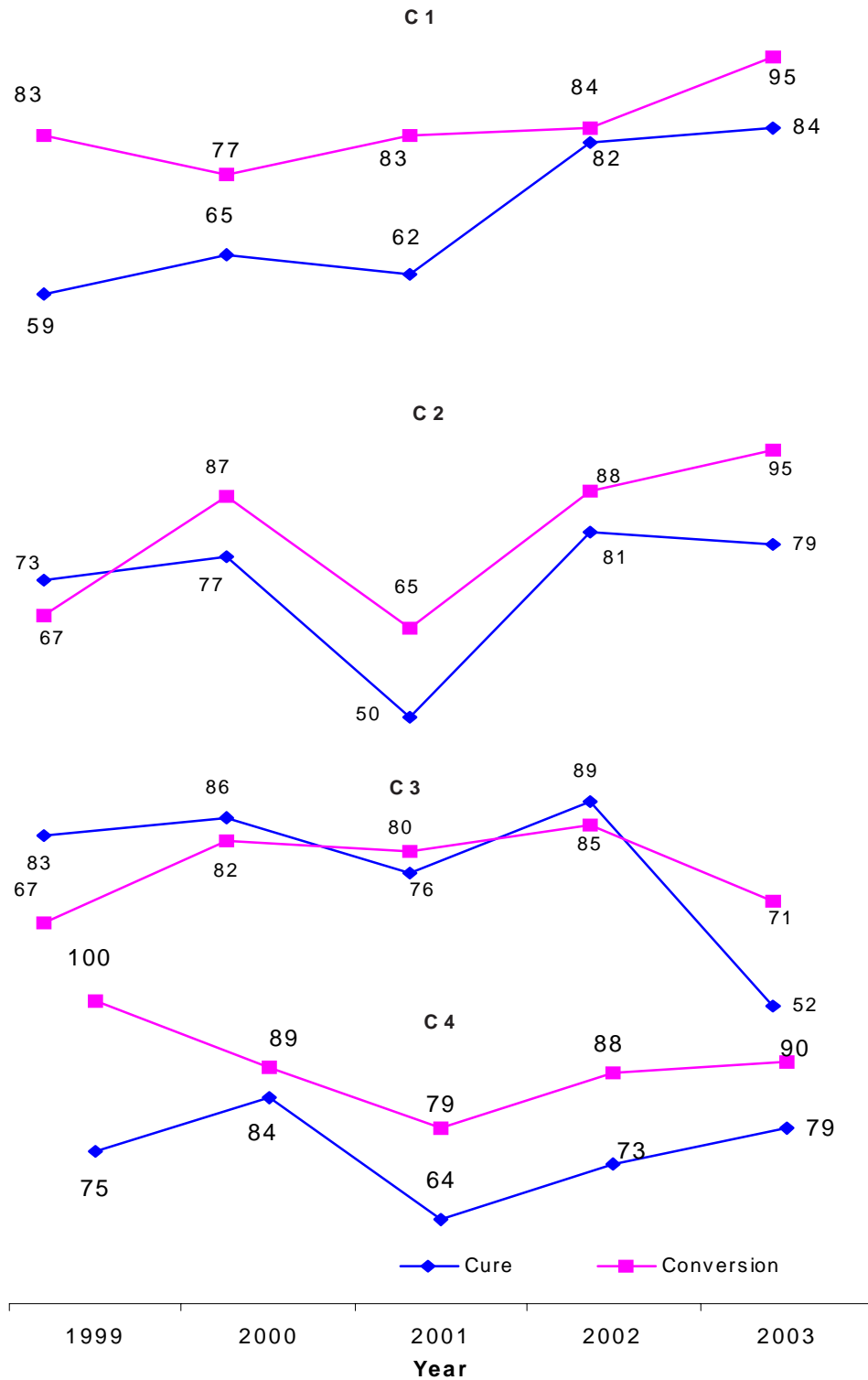
**Fig 1:** Cure and conversion rates from 1999-2003 for new smear positive patients



**Fig 2a:** Cure and conversion rates in each HF under Block A (1999 – 2003)



**Fig 2b:** Cure and conversion rates (%) in each HF under Block B (1999 – 2003)

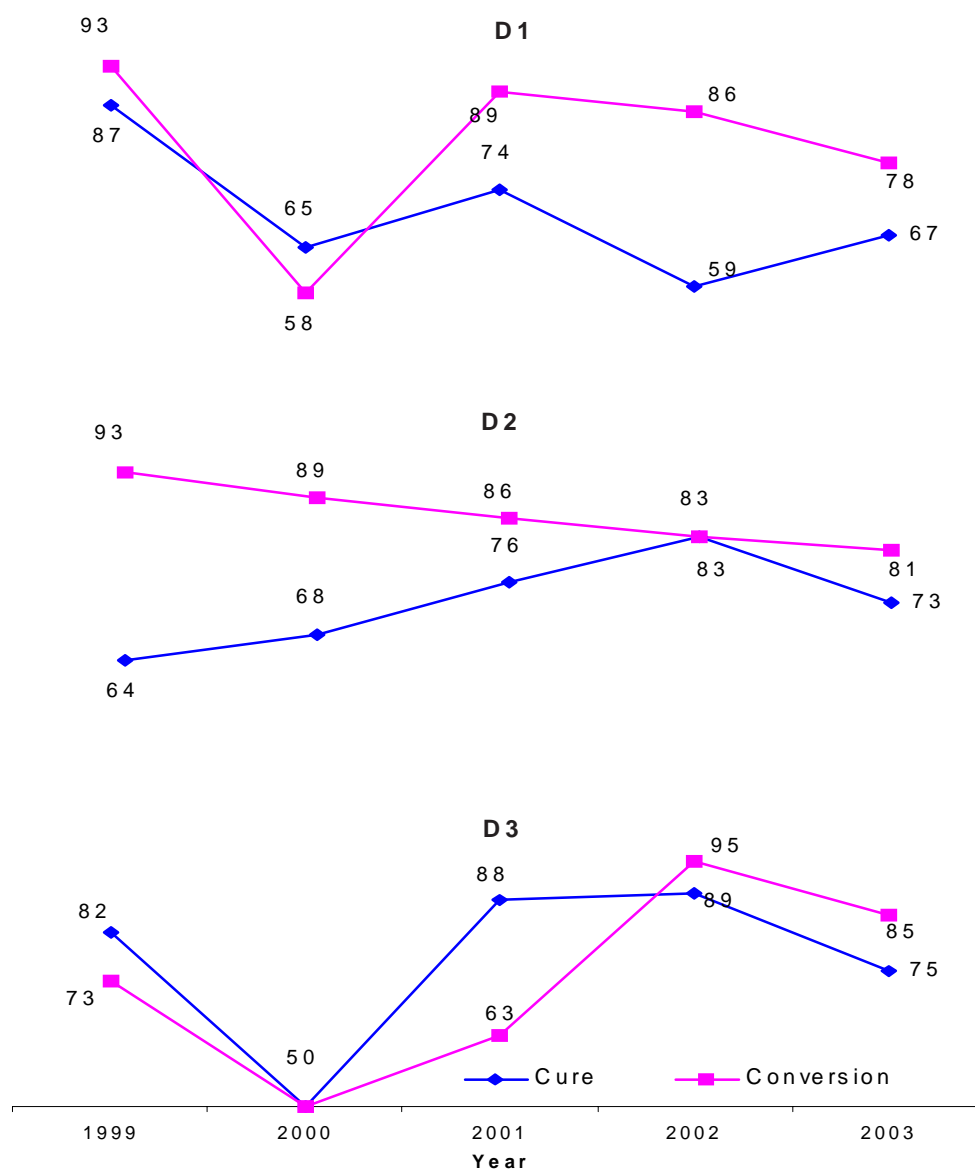


**Fig 2c:** Cure and conversion rates (%) in each HF under Block C (1999 – 2003)

to 87% in 2003 and the trend was statistically significant (Trend  $\chi^2 = 15.9$ ;  $P < 0.001$ ). Similarly, a significant increase in trend (Trend  $\chi^2 = 4.0$ ;  $P < 0.05$ ) was observed in the cure rates 71, 78, 72, 80 and 79% for the years 1999, 2000, 2001, 2002 and 2003 were respectively. Fig 1b, 1c, 1d, 1e and 1f give the performance of the five blocks (A, B, C, D and E), respectively. Block D showed a decrease in the cure and conversion in the year 2000 and blocks A and C in 2001.

In block A, both conversion and cure showed a gradual increase till 2003. In block C there was an increase in cure in 2002, but declined again in 2003. In block D, though cure increased in 2001, it declined again in 2002 and 2003. The low rate for conversion and cure observed in these two blocks was compensated by high rates in the other blocks giving an overall conversion and cure rates of 82% and 78% respectively.

Fig 2a, 2b, 2c, 2d and 2e give respectively



**Fig 2d:** Cure and conversion rates (%) in each HF under Block D (1999 – 2003)

the performance of the HFs under each of the five blocks. In block A, the decline observed in conversion and cure for the year 2001 was contributed by the HF A2. In block B, the decline observed from 2001 in the cure rate was contributed by HF B3 in 2001 and B2 in 2002. The cure and conversion rates were low in HFs C1 (for cure only), C2 and C4 of block C for the year 2001. Similarly in block D, the decline observed for cure and conversion in 2000 was contributed by D1 and D2.

The functional score was correlated to both conversion and cure (Table 2). The correlation coefficient was 0.78 for conversion and 0.83 for cure ( $P < 0.01$ ). A significant increase in trend for both conversion and cure in relation to the functional score was observed except for cure in 2002. In univariate analysis of the eleven parameters (score 1 or 0) for 17 HFs for five years ( $n = 17 \times 5 = 85$ ), all factors except for availability of VHN and Pharmacist were found to be significantly associated with a high conversion

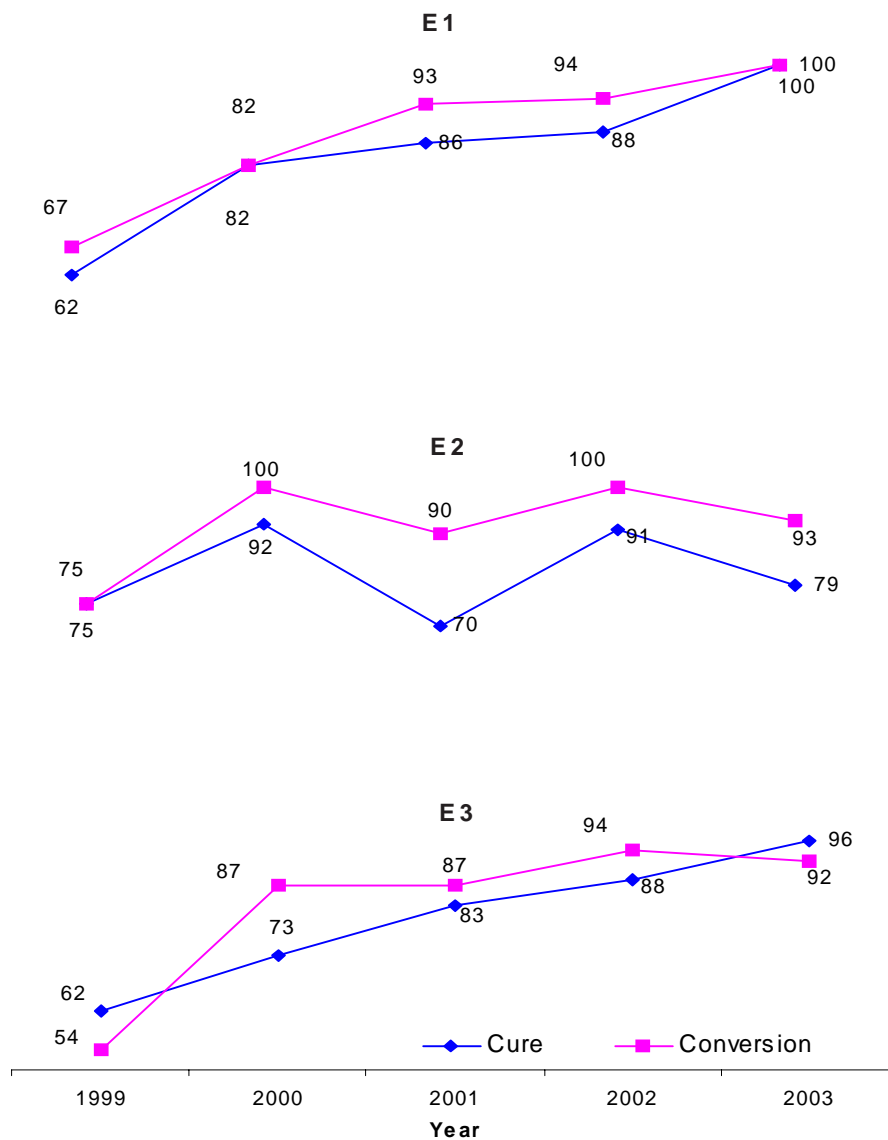


Fig 2e. Cure and conversion rates in each HF under Block E (1999 – 2003)

and cure (Table 3). In multivariate analysis, holding review meeting was independently associated with conversion and cure. Availability of LT was an additional factor found to be independently associated with cure.

## DISCUSSION

The main finding of our study was that the programme performance varied between the HFs in the area over the years and for the first time we are able to correlate the functioning of HF with programme performance. Factors that influence the indicators are regular availability of essential staff such as MO, LT, regular supervisory visits of field staff, and review of DOTS activities. Availability of VHN and Pharmacist appeared to have not contributed significantly towards improving the conversion and cure. This could be due to the decentralization of the DOTS activities and hence their availability would not have contributed much.

In block A, redeployment of staff for the speciality health camps conducted might have affected the DOTS performance. The absence of a MO and lack of review meeting might have contributed to poor performance in some of the HFs for 2001. Speciality health camps and lack of regular review meetings might have contributed for the sub-optimal performance of B3 in 2001. In HF B2, lack of MO, review meetings and supervision in the year 2002 were found to be the factors that might have contributed for a poor performance in 2002. In HF C1, patients not belonging to the area were started on treatment, resulting in high default. In HF C2, there was no permanent MO for 8 months and adequate training was not given for those posted temporarily. In HF C4, the MO was deputed for health camp. The performance improved from 2002 due to the posting of regular MO and regular review meetings. In HF C3, there was no permanent MO in 2003 and hence no supervisory field visit was made during this year. The low conversion and cure rates in block D for the year 2000 might be due to the poor performance of D1 and D3. In HF D1, the MO in-charge was transferred and there was no review on DOTS activities. In 2001, the performance improved but decreased further due to

frequent transfers of MOs and posting of MO who was not trained in DOTS. In HF D3, MOTC did no field visit throughout the year 2000. There was no pharmacist for four months. The performance improved in the subsequent two years. In 2003, the non-availability of MO and diversion from the DOTS activities, might have contributed to the slight reduction in cure and conversion. All HFs of the block E performed well except HF E2 where there was slight decline in the cure rate for 2001. This was due to migration of patients to the neighboring state. HFs A1, A4, B1, B2, C3, and D2 had performed better since the supervision and review meetings were regular in these areas.

There is an existing comprehensive system of monitoring of RNTCP based on indicators that have international acceptance. There is a need to emphasize the need for periodic evaluation of the functioning of each HFs and outreach of services to the patients to ensure that the programme is well functioning with adequate staff and other functionaries to achieve the expected level of cure and conversion<sup>6</sup>. Keeping these in mind, we have attempted to identify HFs not functioned optimally that might have resulted in low conversion and cure rates.

**In our series, there was a correlation between good performance of HFs and the availability of supervisory staff at the HF, supervision and conduct of review meeting. There was a mutual relationship between activities of the HFs in terms of functional scores and programme indicators. The correlation coefficient of 0.8 each obtained between functional score and conversion; and functional score and cure was a quantitative expression of the similarity between HF activities and success of the TB programme. In general, there was a significant increase in trend for both conversion and cure based on the functional score.**

TB can be controlled only with effective supervision and efficient management. One of the major weaknesses of the earlier national TB control programme of India identified in 1992<sup>7</sup>, was lack of supervision. Though, in RNTCP adequate emphasis

has been given for supervision, there is a need to re-emphasize this important component as shown in this analysis. It needs to be stressed that "What gets supervised gets done"<sup>8</sup>. To overcome this there should be a political commitment to have required number of supervisory staff at all levels. The programme should attract the right kind of people to learn and be committed to the programme<sup>9</sup>. The programme has already shown that with careful management, it is possible to treat a large number of patients even in the context of a sub-optimally functioning health care system<sup>10</sup>. A poorly managed TB control programme can worsen the epidemiological situation of TB in our country<sup>3</sup>.

Lack of regular review meetings and supervisory visits by the MO, MOTC and VHN/HI were the main factors that might have contributed to the poor performance of some HFs. It was observed that in these centers either the MO was not available due to transfer, deputation or long leave. During one year, many speciality health camps were organized by the state government, requiring the staff of the HFs to be present in the camps which might have affected the TB programme functioning. Lack of review meetings were independently associated with low conversion and cure.

TB can be controlled if appropriate policies are followed, effective clinical and public health management is ensured, and there are committed and co-ordinated efforts from within and outside the health sector. We have correlated the health functions with the programme indicators by a scoring system. Both were found to be well correlated indicating that success of the DOTS depends on the health functions.

#### **Limitation of the study**

The performance was generally low in the year 1999 when the DOTS was introduced. Since this was in the initial stage of implementation (May-Dec), the conversion and cure were found to be low. The conversion was less than the cure in 1999 as observed in some of the HFs due to small number

of patients. In some of the HFs, during the later years also, the conversion was found to be less than the cure because of small numbers.

The comparison of the programme indicators among different HFs was based on small numbers (as low as 10 in some HF) and it may not be strictly comparable. However, identifying areas with poor performance and exploring the reasons for the same would be useful for monitoring and improving the programme.

There could be some other factors that would have contributed to a low performance of DOTS programme. We have not looked into these factors and hence our observations attributed for a low DOTS performance need not be necessarily true.

**In conclusion, a well functioning programme requires regular availability of essential staff such as MO, LT, and regular supervisory visits in addition to review of DOTS activities will help to motivate the staff involved on a continuous basis to work with dedication. This will be a challenge to improve and sustain the programme with the existing health care system.**

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The Editorial Board of IJT has decided to bring out a series of review articles covering various aspects of extra-pulmonary tuberculosis starting from January 2007 issue onwards. The contributors are requested to kindly send review articles on various aspects of extra-pulmonary tuberculosis well in time.

## ROLE OF LOW LEVEL NITROGEN LASER THERAPY IN CHRONIC DRUG RESISTANT PULMONARY TUBERCULOSIS

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### Summary

**Aim:** In this longitudinal study, the Role of Low Level Laser Therapy in Chronic Drug Resistant pulmonary tuberculosis has been studied for a period of 10 years from 1995 to 2004 and follow up was done for a period of 3 years.

**Material and Methods:** 61 patients in Nitrogen Laser Therapy group (LLLT Group) and 61 were kept as control group. The aim of study was to describe the efficacy and safety of low level nitrogen laser therapy in management of chronic drug resistant pulmonary tuberculosis. All the patients, included in this study, had already taken anti-tubercular drugs for more than one year and were still sputum smear and culture positive.

**Results:** Among LLLT group, 44 (72.13%) patients became sputum smear and culture negative for MTB (*Mycobacterium Tuberculosis*) as compared to 26 (42.62%) in control group. Of the 44 patients, 22(50%) converted within first month.

**Conclusion:** Low Level Nitrogen Laser Therapy may be used as an adjuvant to anti-tubercular drugs in cases of chronic drug resistant pulmonary tuberculosis. [*Indian J Tuberc* 2006; 53:135-140]

**Key Words:** Tuberculosis, Low Level Nitrogen, Laser.

## INTRODUCTION

Tuberculosis affects more than 8 million people and has serious repercussion on economy, psychological and social status. Since the declaration as a global emergency in 1993 by the WHO, significant development in the treatment and control of tuberculosis has been the implementation of the short course directly observed treatment along with fixed dose combination of existing drugs. However, the available therapeutic regimens have inherent disadvantage of long treatment duration, results in patient's non-compliance, and yields the risk of having drug resistance. Hence new modalities of treatment that are potent, active resistant against strain and curtailment of treatment period are needed to combat this disease. In countries that are poor MDR cases, which cannot be treated with the standard medicine, can be a death sentence. MDR - PTB (Multi Drug Resistant Pulmonary Tuberculosis) is at least 50 times more expensive than CAT-1 regimen. Drugs available to treat MDR TB are weak, and have more adverse reactions.

Lungs of patients affected by TB, a single founder strain of *Mycobacterium Tuberculosis*, may undergo mutagenesis during treatment, leading to drug resistance independently in discrete physical locales, resulting in parallel evaluation of heterogeneous sub-population of drug resistant bacilli. Relying on drug susceptibility test of organisms isolated from patient sputa may not provide an accurate representation of the bacterial susceptibility in all sub-populations within the lung.

The growth of MTB is well known to occur in proportion to oxygen tension. Thus another factor contributing to the florid bacterial growth seen at the luminal surface of the cavity could be improved access to oxygen in the micro-environment.

The risk of spreading infection to the other sites in the same patient and to non-infected persons from an individual with cavitary tuberculosis is very high. There is difficulty in reaching adequate drug concentration because of lack of adequate circulation.

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In continuation of the pioneering work of Finsen on treatment of skin TB by UV<sup>1</sup> light and *in vitro* reports on bactericidal effect of UV light on tubercular bacilli<sup>2</sup>, Eshanchanov *et al* reported the use of UVA radiation from nitrogen laser (337 nm) for the treatment of patients with PTB<sup>3</sup>. *In vitro* experiments have also been carried out to understand the therapeutic mechanism involved. It has been shown that nitrogen laser irradiation can inhibit growth of tubercular bacilli particularly at high intensities<sup>4</sup>. *In vitro* experiments have also provided some evidence as potential implements of nitrogen laser irradiation on the immune system, e.g. nitrogen laser irradiation was seen to enhance the intracellular killing of internalized bacterial in human neutrophil<sup>5</sup>. Nitrogen laser irradiation leads to temporary inactivation of drug sensitive as well as drug resistant clinical isolates of MTB<sup>6</sup>. Laser therapy improves the blood circulation and essentially increases oxygen supply and so stimulates mycobacteria to reproduction, making infecting agents relatively easily available for anti-tubercular drugs. The present study has been carried out to describe the efficacy and safety of low level nitrogen laser therapy in management of Chronic Drug Resistant pulmonary tuberculosis.

## MATERIAL AND METHODS

One hundred twenty two patients with drug resistance pulmonary tuberculosis admitted to single medical unit of Department of Medicine, M.G.M. Medical College & M.Y.Hospital, Indore, over a 10 year period from 1995 to 2004 were included in a retrospective pattern.

The study was conducted with the consent of all patients. Their detailed medical history and physical examinations were taken from them and included in the study conducted between age-group 15-65 years with diagnosis of drug resistant tuberculosis. Drug resistance proven by (a) AFB culture and sensitivity; (b) received anti-tubercular treatment for more than 1 year showing no response and (c) presence of cavity in chest X-ray.

Baseline investigation included complete haemogram, blood sugar, sputum examination for

presence of acid fast bacilli, AFB culture and sensitivity, screen test for human immunodeficiency virus, Australia - antigen for hepatitis - B virus, Skiagram chest and CT chest.

## Intra-cavitary laser irradiation

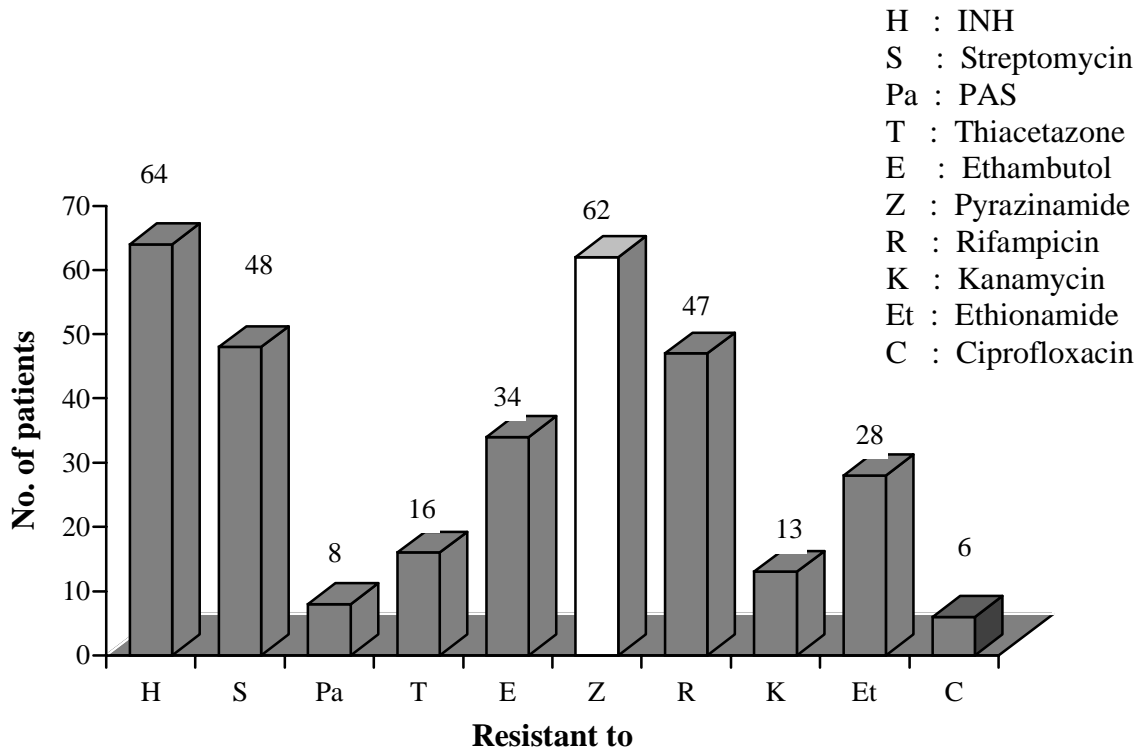
Intra-cavitary nitrogen laser was given at the site of lesion or cavity. Cavities were localized topographically using percussion and auscultation, chest radiography and CT scan were done to localize the cavity. The anatomical site of entry was localized between the inter-costal space nearest to the chest wall and then the patient was positioned accordingly, either sitting or supine, depending on the site of puncture. The patient was given 0.6 mg of atropine intra-muscularly 20 minutes before the procedure. With all aseptic precaution, local anesthesia was given and a 10 ml syringe filled with normal saline and fitted with a 126 G 50 mm jelco cannula was introduced at the site, negative pressure was created by pulling back the piston while pushing the needle forward. Few bubbles of air entry into the syringe confirmed the entry of the jelco cannula into the cavity. The syringe with the guide needle was immediately withdrawn and the optical fibre was introduced and fixed at the site. Laser machine started. 2mW nitrogen laser was given for 780 sec, once weekly for total 10 sittings. The nitrogen laser used was pulse nitrogen (2 mw average power, at a wavelength of 337.1 nm, a repetition rate of 10 Hz, energy per pulse of 10-30  $\mu$ J and a pulse width of 7 nanoseconds) Nitrogen laser was coupled into a fibre optic with a diameter of 200  $\mu$ m and an angle of divergence in the order of 20° would imply an energy density of approx. 1.6 J/cm<sup>2</sup> at the fibre tip and approx. 0.82 mJ/cm<sup>2</sup> at a distance of 5 cm from the fibre tip assuming a spherical cavity. Therefore, 780 seconds exposure time results in dose of approx. 980 J/cm<sup>2</sup> at the fibre tip and approx. 492 mJ/cm<sup>2</sup> at the distance of 5 cm from the tip. Appropriate statistical test of significance was used in analysis of data ( $\chi^2$  test)

## RESULTS

In the present study, 122 patients were taken, including 61 patients in nitrogen laser therapy

group and 61 were kept as control group. Male to female ratio was 1.71:1. Mean age of patient was 30.78 (Table 1), mean duration of illness before receiving therapy was 3.19 yrs. (Table 2). The most common

drug resistance was found to be of Isoniazid, followed by Pyrazinamide, Streptomycin and Rifampicin. In our study least resistant was found to be of Quinolone group (Ciprofloxacin) (Figure-1).



**Fig:** Pattern of drug resistance according to culture sensitivity report

**Table 1:** Age wise distribution of cases among LLLT Group and Control Group

Age (in yrs.)	LLT Group		Control Group	
	No.	%	No.	%
15-25	20	32.78	21	34.42
26-35	26	42.62	23	37.70
36-45	11	18.03	11	18.03
46-55	3	4.91	6	9.83
56-65	1	1.63	0	0
<b>Total</b>	<b>61</b>	<b>100</b>	<b>61</b>	<b>100</b>

(z test, z=0.09; p> 0.10; Insignificant)

**Table 2:** Duration of illness before receiving treatment among LLLT Group and Control Group

Duration (in months)	LLT Group		Control Group	
	No.	%	No.	%
12-24	29	47.54	37	60.65
25-36	15	24.59	7	11.47
37-48	3	4.91	6	9.83
49-60	5	8.19	5	8.19
> 5 yrs	9	14.75	6	9.83
<b>Total</b>	<b>61</b>	<b>100</b>	<b>61</b>	<b>100</b>

(z test, z=1.45; p> 0.05; Insignificant)

**Table 3:** Time taken for sputum conversion in LLLT Group and Control Group

Sputum Conversion Positives to negatives	LLLt group		Control group	
	No.	%	No.	%
1st month	22	50.00%	7	26.92%
2nd month	12	27.27%	9	34.61%
5th month	6	13.63%	2	7.69%
6th month	3	6.81%	5	19.24%
8th month	1	2.27%	3	11.53%
<b>Total</b>	<b>44</b>	<b>72.13%</b>	<b>26</b>	<b>42.62%</b>
Not Improved	17	27.86%	35	57.37%
<b>Grand Total</b>	<b>61</b>	<b>100%</b>	<b>61</b>	<b>100%</b>

Sensitivity is 72.13%, specificity 57.37%,  $\chi^2$  test; p value <0.05 significant.

Table 3 shows that out of 61 patients, 44 (72.13%) became sputum smear and culture negative for MTB among LLLT group as compared to 26(42.62%) in control group. Among LLLT group, 22 patients (50%) converted within 1<sup>st</sup> month as compared to 7 cases (26.92) in control group. Sputum conversion is faster and maximum during the first month of laser therapy (50%).

Improvement was observed according to drug resistance pattern (Table 4). Of the 61 patients, 44 (72.13%) among LLLT group as compared to 26(42.6%) in control group showed improvement. Improvement was maximum in patients of single drug resistance.

**Table 4:** Improvement according to Drug Resistance

Drug Pattern	LLLt Group			CONTROL		
	Improved	Not improved	Total	Improved	Not improved	Total
Single drug resistance	12(85.71%)	2(14.28%)	14	5(71.42%)	2(28.57%)	7
Two drugs resistance	7(70%)	3(30%)	10	5(50%)	5(50%)	10
Three drugs resistance	7(70%)	3(30%)	10	6(40.00%)	9(60.00%)	15
More than three	18(66.66%)	9(33.33%)	27	10(34.48%)	19(65.51%)	29
<b>Total</b>	<b>44(72.13%)</b>	<b>17(27.86%)</b>	<b>61</b>	<b>26(42.62%)</b>	<b>35(57.37%)</b>	<b>61</b>

Sensitivity is 72.13 %, specificity is 57.37 % ,  $\chi^2$  test; p <0.05 significant.

**Table 5:** Improvement according to radiological findings

X-ray findings	LLLt GROUP			CONTROL GROUP		
	Improved	Not improved	Total	Improved	Not improved	Total
Single cavity	13(81.25%)	3(18.75%)	16	12(70.58%)	5(29.41%)	17
Two cavities	3(75%)	1(25%)	4	1(33.33%)	2(66.66%)	3
Multiple cavities with fibrosis	23(74.19%)	8(25.80%)	31	8(25%)	24(75%)	32
Unilateral destroyed lung with F/C lesion opposite lung	4(40%)	6(60%)	10	1(11.11%)	8(88.88%)	9
<b>Total</b>	<b>43(70.49%)</b>	<b>18(29.50%)</b>	<b>61</b>	<b>22(36.06%)</b>	<b>39(63.93%)</b>	<b>61</b>

Sensitivity is 70.5% , specificity is 63.9% ,  $\chi^2$  test; p value is < 0.05 significant.

Out of 61 patients, 43 (70.41%) improved radiologically as compared to 22 (36.06%) in control group (Table 5). Maximum improvement was seen in single cavity. Radiological improvement was seen in terms of complete closure of cavity in 20% of improved patients and regression of cavity and thinning of the wall of cavity in 42.85% of improved patients. Rest of the patients' cavity size remained as such.

Five patients had slight Haemoptysis, 7 developed pneumothorax, all were managed conservatively.

All patients, who completed full course of treatment, were followed up for an average period of 3 years. Seven patients (11.47%) showed bacteriological relapse while 4 (6.55%) relapsed within 6 months and 3 (4.91%) relapsed after 12 months after completion of treatment.

## DISCUSSION

Multi drug resistant pulmonary tuberculosis (MDR-PTB) is one entity which presently has no other modality of treatment except the second line drugs like Cycloserin, Kanamycin, Ethionamide, Prothionamide, PAS and so on, which in a developing country like India is a costly affair. Also these drugs are not freely available, therefore the patients' compliance becomes poor. The use of alternative modalities of treatment for tuberculosis like UV radiation, electrotherapy, and drugs like iodoform and formaldehyde have been recognized for over one hundred years. Before the advent of chemotherapeutic drugs, agents like iodoform and formaldehyde have been used in treatment of phthisis (tuberculosis) with some success. Radioactive agents such as radium thorium have also been used in treatment of tuberculosis as early as 1903 by Soddy et al. Hence it was proven that apart from chemotherapeutic drugs, alternative modalities of treatment have a role in treatment.

Although the exact mechanism by which beneficial effects of LLLT observed in

tuberculosis is not known but it has been observed that nitrogen laser irradiation leads to temporary inactivation of drug sensitive as well as drug resistant clinical isolate of MTB6. UVA radiation has been reported to lead to alteration in cell membrane properties *via* damage to membrane lipid<sup>7-9</sup>. Nitrogen laser irradiation alters the fluidity of lipid region of the cell wall<sup>6</sup>.

Another important aspect concerning Nitrogen laser irradiation (337nm) induced inactivation of MTB is that UV (320-400nm) irradiation of cell is known to lead to generation of oxygen radicals as singlet oxygen photosensitized reaction involving endogenous photochromophore<sup>10</sup>.

Out of 61 patients, 44(72%) became sputum smear and culture negative for MTB in LLLT group. Among those who achieved Bacteriological conversion, 22 patients (50%) converted within first month as compared to 26.92 in control. Sputum conversion rate is higher and faster in LLLT group as compared to control group. Similar studies were also conducted in Tashkent by Eshankhanov<sup>3</sup> et al and in India by Bhagwanani et al<sup>11</sup>, Puri M.M.<sup>12</sup>, yielding similar results.

Maximum improvement was seen in younger age group with resistant to one drug and single cavity. Patients who completed treatment were followed up for 24 to 36 months. 7 patients showed bacteriological relapse because of poor drug compliance and multiple cavities.

**Laser therapy for MDR-PTB is a newer modality of treatment which gives patients a ray of hope for better quality of life. Results are encouraging and LLLT is well tolerated by the patients. Further work is now required to evaluate the basic mechanism of action of laser and optimize the parameter as far as dose delivery and duration of laser irradiation is concerned.**

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## INFLUENCE OF DRUG SUSCEPTIBILITY ON TREATMENT OUTCOME AND SUSCEPTIBILITY PROFILE OF 'FAILURES' TO CATEGORY II REGIMEN

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### Summary

**Objective:** To assess the influence of drug resistance on treatment outcome among patients treated with Category-II regimen and document drug susceptibility pattern of "Failures" to this regimen.

**Design:** A retrospective analysis of patients registered from May 1999 through December 2004.

**Results:** Treatment success was 42% among 572 patients and was similar among patients with fully susceptible or resistant but non-MDR organisms (41% of 254 and 40% of 128 patients, respectively). Among 49 MDR-TB patients, 27% had successful treatment outcome. The failure rates among patients with fully susceptible, resistant but non-MDR and MDR bacilli, were 6%, 12% and 27% respectively. Default was significantly higher among males (53% vs. 34%:  $p < 0.01$ ) smokers (57% vs. 36%:  $p < 0.001$ ), alcoholics (58% vs. 39%:  $p < 0.001$ ) and patients with higher initial smear grading (2+ or 3+, 56% vs. scanty or 1+, 44%:  $p < 0.01$ ). DST results were available for 60% (31 of 52) of failures and 10 had MDR-TB.

**Conclusion:** The low success rate to the re-treatment regimen was mainly due to non-compliance. Failure was observed among 9% of patients and MDR-TB was 32% among Category II failures. The currently recommended Category II regimen appears to be adequate for majority of re-treatment cases. [Indian J Tuberc 2006; 53:141-148]

**Key words:** Treatment outcome, Category II regimen, failure, RNTCP, MDR-TB

### BACKGROUND

The Revised National Tuberculosis Control Programme (RNTCP) based on the globally recommended Directly Observed Treatment-Short-course (DOTS) strategy was implemented in India in a phased manner since 1993. Treatment outcome among new smear-positive pulmonary tuberculosis (PTB) patients to category-I regimen has been reported to be good with a success rate of 83% or higher at national level<sup>1,2</sup>. For previously treated patients, the success rate to the re-treatment regimen (CAT-II) was low (71%). Among patients typed as 'failure' and treated with re-treatment regimen, risk of subsequent failure was higher, compared to other types<sup>1,2</sup>.

There is concern regarding the effectiveness of category-II (CAT-II) regimen for re-treatment cases especially for 'Failures'<sup>3,4</sup>. Whether or not this re-treatment regimen is appropriate depends on the prevalence of drug resistance among these cases and treatment adherence. In India, it is reported that,

1-3.4% of new patients have had multi-drug resistant TB (MDR TB)<sup>5</sup>. Studies on acquired resistance have shown rates of resistance to Isoniazid ranging from 34.5-67%, for Streptomycin around 25% and for Rifampicin from 2.8-37.3%<sup>6</sup>.

Tuberculosis Research Centre (TRC) has been monitoring the DOTS programme in one Tuberculosis Unit (TU), Tiruvallur district, Tamil Nadu. This paper describes the treatment outcome among different types of patients admitted to the re-treatment regimen, the influence of drug resistance on treatment outcome and the drug susceptibility pattern among patients who failed to this regimen.

### METHODOLOGY

Tuberculosis Research Centre (TRC) is undertaking a series of epidemiological surveys (Disease and tuberculin surveys to estimate prevalence of TB and infection) in an area of Tiruvallur district since 1999. RNTCP was implemented by Government of Tamil Nadu in this

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area and TRC was monitoring the same up to 2004 December. Monitoring and follow up were done according to RNTCP guidelines<sup>7</sup>. Definitions recommended under RNTCP were followed to define treatment outcomes. As an operational study, we have been conducting Drug Resistance Surveillance (DRS) of patients treated under RNTCP in this area. Drug sensitivity testing (DST) was done for all patients at the initiation of treatment and whenever they produced a positive smear during the treatment period. HIV screening was not done since it is not recommended under RNTCP. This paper gives the findings of a retrospective analysis of patients registered under category II regimen of RNTCP.

### Study area and population

The study area has a population of 580,000 spread over 209 villages and 9 urban clusters, situated about 45 kilometres from Chennai. The area has 17 governmental health care facilities, including 7 designated microscopy centres. Smear positive patients, with history of previous anti-tuberculosis treatment for more than one month, comprising cases of 'Failure', Treatment after Default ('TAD'), and 'Relapse' started on the CAT-II regimen from 1999 to 2004, constituted the study population. For outcome of treatment, we have included patients registered up to December 2003 since TRC was monitoring the programme only up to December 2004.

### Setting

Patients attending any of the health facilities with a history of cough for 3-weeks or more, were screened for tuberculosis by sputum smear microscopy (Ziehl-Neelsen method). Diagnosis, treatment and monitoring were done according to RNTCP guidelines<sup>7,8</sup>. The standard re-treatment regimen of RNTCP in India consists of 3 months of Isoniazid (H), Rifampicin(R), Pyrazinamide(Z), and Ethambutol(E), with addition of Streptomycin (S) in the initial two months, followed by 5 months of R, H and E (2SHRZE<sub>3</sub>/1EHRZ<sub>3</sub>/5HRE<sub>3</sub>) given three times a week, throughout the 8 months period. Patients whose sputum smears remained positive at the end of intensive phase of three months, treatment

with R, H, Z and E was extended for one more month.

### Drug sensitivity testing

Two additional sputum specimens were collected for drug sensitivity tests (DST) within one week of starting treatment and whenever they produced a positive sputum by smear microscopy, during treatment. The sputum samples were processed for culture for *M. tuberculosis* on Lowenstein - Jensen medium<sup>9</sup>. Cultures positive for *M.tuberculosis* were subjected to indirect sensitivity test for H, R, E and S. The resistance to H and R was determined by absolute concentration method (MIC) and to S by Resistance Ratio (RR) methods<sup>10,11</sup>. An MIC of 5mg/L or more, 8mg/L or more and an MIC of 128mg/L or more were defined as resistance for H, E and R respectively and an RR of 8 or more was considered as resistance to streptomycin..

### Statistical analysis

The data were scrutinized for completeness and all the records were keyed in twice. Chi-square test of significance was performed to test the difference between different proportions. Yates corrected two-tailed P values  $\leq 0.05$  were considered as significant. The potential risk factors for default were studied by univariate analysis using Epi Info version 6.04 d (Centers for Disease Control, Atlanta, GA, 2001).

## RESULTS

From May 1999 through December 2004, a total of 697 smear-positive patients were started on re-treatment with CAT-II regimen. The proportion of smear-positive re-treatment cases to the total smear-positive cases ranged from 24.5% in 1999 to 22.8% in 2004. The 697 patients included - 32% cases of 'Relapse', 20% 'Failure' and 47% 'TAD' cases.

### Treatment outcome according to 'type' of cases

Of the 697 smear-positive patients registered

**Table 1:** Treatment outcome of 572 re-treatment cases registered to CAT II regimen.

Type of Cases	No.	Treatment Outcome									
		Success		Failure		Defaulted		Died		T- out	
		No.	%	No.	%	No.	%	No.	%	No.	%
Relapse	187	96	51	15	8	66	35	9	5	1	1
Failure	111	36	32	15	14	51	46	9	8	0	0
TAD	274	106	39	22	8	123	45	23	8	0	0
Total	572	238	42	52	9	240	42	41	7	1	0.002

to CAT-II regimen, 575 patients whose treatment outcome was available by December 2004 are included in the analysis (Table 1). (Three cases belonging to the type "others" were excluded from analysis, since the number was very few and they could not be combined with any other group for analysis.). Of the total 572 cases, 238 (42%) had a successful treatment outcome (cure-41%, treatment completed-1%) and 240 (42%) defaulted. 'Relapse' cases had a significantly higher cure rate (51%) compared to 'Failure' and TAD cases ( $p < 0.01$ ). Fifty-two (9%) patients failed to the re-treatment regimen; 14% (15 of 111) among 'Failures', 8% (15 of 187) among 'Relapses', and 8% (22 of 274) among 'TAD' cases. However the difference was not statistically significant. The time at which patients defaulted were available for 219 out of the total 240 from the treatment cards and 49% defaulted within the first 3 months of treatment. The rate and time of default were almost similar in all types of patients. Forty-one (7%) patients died during the course of the treatment. Of the 37 patients for whom information is available, 70% died within 3 months of starting treatment.

#### Response to treatment according to drug susceptibility pattern

Of the 572 cases included in this analysis, even though it was planned to collect sputum specimens from all patients, specimens could not be collected from 50 (9%) patients within one week of treatment initiation due to operational reasons. Among 431 patients who produced positive cultures, 254

(59%) harboured sensitive bacilli, 128 (30%) resistant but non-MDR bacilli, and 49 (11%) had MDR-TB (Table 2). There was no growth in the culture for 91 (17%) patients. Among 254 patients harbouring sensitive bacilli and 128 with resistant but non-MDR bacilli, the cure rates (41%, 40%) were almost similar. Among 49 patients with MDR-TB, 13 (27%) had a favourable outcome. The failure rates were 6%, 12% and 27% among patients with fully susceptible, resistant but non-MDR and MDR bacilli, respectively. The failure rate was highest among patients with MDR-TB ( $p < 0.05$ ). The default rate was high and almost similar in all groups (46%, 38%, and 39%), irrespective of the drug susceptibility profile. The MDR-TB observed was 9% (20 of 226), 22% (14 of 63), and 11% (15 of 142) among TAD, 'Failures', and 'Relapses' respectively (Table 2). The MDR-TB observed among 'Failures' was significantly higher (22%) compared to that observed in the other two types of patients ( $p < 0.05$ ).

Among the 91 (17%) patients who produced no growth in the culture, 56% had a successful treatment outcome, 35% defaulted, 3% died and 5% failed. Of the 111 'Failure' cases registered to the CAT-II regimen, sputum specimens were collected from 94 cases. Thirty-one of the 94 (33%) 'Failure' cases did not show any growth in the culture. Considering all 94 'Failure' cases for whom sputum specimens were collected, MDR-TB could be documented in 14 (15%) of the cases, compared to 22% considering only patients with growth in culture. The culture negativity among TAD and Relapse cases was 12% (30/256) and 17% (30/172) respectively.

**Table 2:** Treatment outcome related to drug sensitivity pattern (n=431)

Drug sensitivity results	Success		Default		Died		Failed		Total	
	No.	%	No.	%	No.	%	No.	%	N	%*
<b>TAD</b>										
Sensitive	55	38	68	47	11	8	10	7	144	64
Resistant (non-MDR)	24	39	23	37	7	11	8	13	62	27
HR resistant	6	(30)	8	(40)	2	(10)	4	(20)	20	9
<b>Total</b>	<b>85</b>	<b>38</b>	<b>99</b>	<b>44</b>	<b>20</b>	<b>9</b>	<b>22</b>	<b>9</b>	<b>226</b>	
<b>Failure</b>										
Sensitive	4	(21)	12	(63)	2	(11)	1	(5)	19	30
Resistant (non-MDR)	11	37	12	40	4	13	3	10	30	48
HR resistant	1	(7)	6	(43)	2	(14)	5	(36)	14	22
<b>Total</b>	<b>16</b>	<b>25</b>	<b>30</b>	<b>48</b>	<b>8</b>	<b>13</b>	<b>9</b>	<b>14</b>	<b>63</b>	
<b>Relapse</b>										
Sensitive	46	51	37	41	5	5	3	3	91	64
Resistant (non-MDR)	16	42	13	36	3	8	4	11	36	25
HR resistant	6	(40)	5	(33)	0	(0)	4	(27)	15	11
<b>Total</b>	<b>68</b>	<b>48</b>	<b>55</b>	<b>39</b>	<b>8</b>	<b>6</b>	<b>11</b>	<b>8</b>	<b>142</b>	
<b>Grand Total</b>										
Sensitive to H&R	105	41	117	46	18	7	14	6	254	59
Resistant but non-MDR	51	40	48	38	14	11	15	12	128	30
HR resistant	13	27	19	39	4	8	13	27	49	11
<b>Total</b>	<b>169</b>	<b>39</b>	<b>184</b>	<b>43</b>	<b>36</b>	<b>8</b>	<b>42</b>	<b>10</b>	<b>431</b>	

\*Percentage to the column total

Figures in parenthesis indicate the denominator <25

We analysed risk factors for default for 42% of patients who had defaulted. In univariate analysis, of treatment success vs default, a higher default was significantly associated with sex {66% (47 of 71) among females vs 47% (193 of 410) among males:  $P<0.01$ }, smoking {64% (106 of 166) among non-smokers vs 43% (83 of 195) among smokers:  $P<0.001$ }, alcoholism {56% (112 of 199) among non-users vs 42% (68 of 162) among users,  $P<0.001$ } and initial smear grading {56% (112 of

216) with scanty or 1+ smears vs 44% (118 of 265) with 2+ or 3+ smears,  $P<0.01$ }.

#### **Sputum smear-positivity at the end of 3 or 4 months of treatment**

Of the 572 re-treatment patients, sputum smear results at the end of three months were not available for 153 (27%) patients (126 defaulted and 27 died during the intensive period). One hundred (17%) remained sputum smear-positive at the end

**Table 3.** Sputum smear-positivity at the end of 3 or 4 months of treatment

Type of patients	Sputum smear results after starting treatment							Total No.
	End of 3 months			End of 4 months				
	Negative No %	Positive No %	N.A. No %	Negative No	Positive No	N A No		
TAD	143 52	45 16	86 31	15	13	17	274	
Failure	51 46	34 31	26 23	8	15	11	111	
Relapse	125 67	21 11	41 22	8	6	7	187	
Total	319 56	100 17	153 27	31	34	35	572	

of three months of treatment (Table 3) and intensive phase of treatment was extended for one more month. Of these 100 patients, 34 patients remained sputum smear positive at the end of four months of treatment. A higher proportion (31%) of 'Failure' cases remained sputum smear positive at the end of 3 months of treatment compared to other types of patients (16% for TAD, 11% for Relapses). Of the 100 patients who remained sputum smear-positive at the end of 3 months of treatment, 26% were cured, 25% failed, 6% died and 43% defaulted.

**Drug susceptibility profile among patients with positive smear during treatment**

Of the 100 patients who remained sputum smear positive at the end of three months of treatment, 26% (24 of 91 patients) had MDR-TB at the time of starting treatment. At the end of third month of treatment, of the 53 cases for whom sputum was collected, 12 (23%) had MDR-TB and 17 (32%) had no growth on the culture (Table 4). At the end of 4 months of treatment, 34 (6%) patients

**Table 4:** Drug susceptibility profile of patients who produced positive sputum at 3 months, 4 months and at the time of failure

Sensitivity pattern	Positive at 3-m (N=100)		Positive at 4-m (N=34)		Failed (N=52)	
	Initial	At 3-m	Initial	At 4-m	Initial	At Failure
Sp. not collected	8	45	3	11	5	18
Cul. Contaminated	1	2	1	1	0	3
<b>Total</b>	<b>9</b>	<b>47</b>	<b>4</b>	<b>12</b>	<b>5</b>	<b>21</b>
	No. %	No. %	No. %	No. %	No. %	No. %
Cul Neg.	12 13	17 32	2 7	2 9	5 11	4 13
H & R – Sensitive	28 31	12 23	6 20	3 14	15 32	9 29
Resistant but Non-MDR	27 30	12 23	12 40	8 36	14 30	8 26
<b>RH resistant</b>	<b>24 26</b>	<b>12 23</b>	<b>10 33</b>	<b>9* 41</b>	<b>13 28</b>	<b>10* 32</b>
<b>Total</b>	<b>91</b>	<b>53</b>	<b>30</b>	<b>22</b>	<b>47</b>	<b>31</b>

Figure in parenthesis indicates the denominator <25

\*Including one patient in each who was initially non-MDR (both H resistant)

remained sputum smear positive. The drug sensitivity results showed that, 33% of 30 cases (sputum not collected from four cases) had MDR-TB initially and at fourth month, of the 22 cases for whom DST results were available, 9 (41%) had MDR-TB including one who was initially non-MDR, and 9% had negative culture.

Fifty-two patients who remained smear positive at the end of fifth month or later during treatment were declared 'failed' to the CAT-II regimen. Drug susceptibility profile at the initiation of re-treatment is available for 47 and 13 (28%) had MDR-TB. At the time of failure, of the 31 cases for whom sputum specimens were collected, 10 (32%) had MDR-TB (including one who was initially non-MDR). Of these 52 'Failures', 27 patients had converted to sputum smear negativity at the end of intensive phase.

## DISCUSSION

The proportion of smear-positive re-treatment cases in this DOTS implemented area, over a period of 5 years, from 1999 through 2004, did not show any significant changes and it ranged from 24.5% in 1999 to 22.9% in 2004. Among the re-treatment TB patients, nearly 50% constituted patients who came for re-treatment after defaulting to the previous regimen.

The low success rate (42%) to the CAT-II regimen was mainly due to the high default (42%) during treatment. If all these defaulted patients (240) also had been regular for treatment, the treatment success would have been 72%. Another important finding revealed in this analysis is that the prevalence of drug resistance (non-MDR as well as MDR) was almost similar initially and at the time of failure. Development of resistance to Rifampicin among patients who failed to CAT II regimen was low (2 patients with initial resistance to H emerged resistance to R.)

The favourable outcome to the re-treatment regimen was similar among patients with TB due to susceptible and resistant but non-MDR bacilli. The failure rates were 6%, 15% and 27% among patients

with fully susceptible, resistant but non-MDR and MDR bacilli, respectively, suggesting the re-treatment regimen had been effective in a majority of patients. However, it may not be adequate for patients with multi-drug resistant TB. Similarly in a retrospective cohort study of patients enrolled into the WHO / IUATLD global project on drug resistance surveillance in 6 countries, Espinal et al<sup>12</sup> has reported that of the 876 re-treatment cases, 44.5% were drug resistant, including 19% of MDR-TB. Among them, 57% had a successful outcome, 6% died, and 14% failed. And failure rates among re-treatment cases were higher in those with multi-drug resistant TB and with any Isoniazid resistance other than multi-drug resistance.

High default rate (42%) was the major reason for the low cure rate in this area. Default rate was similar in all groups of patients, irrespective of the type of patients or their drug resistance pattern. The success rate (42%) for the re-treatment cases in this report is significantly low compared to the national average of around 70%<sup>1,2</sup>. However, our findings are comparable to that reported by Sophia Vijay et al<sup>13</sup> from Bangalore (resistance to any drug 40%, MDR-TB 12.8%, cure rate 39.8%, default rate 43.8%).

There is concern regarding the efficacy of CAT-II regimen for re-treatment of TB patients especially for 'Failure' cases, since a high proportion of them may be having MDR-TB. The prevalence of multi-drug resistant TB in re-treatment patients in this area was 11% and it was higher (22%) among 'Failure' cases. Few studies have reported very high rates of MDR-TB in patients who fail to CAT-I regimen. A case-control study from Peru,<sup>14</sup> reported a cure rate of 93% to CAT-I (2EHRZ/4R<sub>2</sub>H<sub>2</sub>), and nearly 75% MDR-TB among failures to this regimen. Treatment failure in urban Lima has been identified as a strong predictor of MDR-TB. Quy et al<sup>15</sup> from Vietnam has reported that of the 40 failure cases to CAT-I regimen (2SHRZ/6EH), 80% had MDR-TB. Among 39 relapse cases, 8% had MDR-TB. Cure rate among relapse cases was 82.5%, while among 119 failure cases, the cure rate was 47% with 39% of patients failing to the regimen. A report from Malawi<sup>16</sup> has reported a treatment outcome of 65% for patients with recurrent TB, 81% of CAT-II

patients had susceptible organisms and MDR-TB was observed only in 4% of cases. In a retrospective study Gninafon et al<sup>17</sup>, from Cotonou, Benin, has reported satisfactory and comparable success rates among re-treatment patients (78%) and new cases (82%). The success rate was similar among relapses (80%) and failures (85%). The failure rate for all re-treatment patients was low (3%). The reasons attributed for the excellent results by the authors were the low rate of both primary (0.3%) and secondary (11%) multi-drug-resistance and Rifampicin was given only under strict supervision. Response to the WHO-recommended re-treatment regimen varies great deal between countries, depending on the prevalence of drug resistance among these patients and the quality of TB control.

Treatment compliance is the most crucial factor for the successful outcome of any effective regimen. Default was significantly more among male patients, alcoholics and smokers. These groups of patients need to be targeted with additional health education and intensive counselling and supervision.

In TB cases with MDR-TB the standard retreatment regimen result in unacceptably high failure rates<sup>12</sup> and for all other drug resistant forms of TB, Rifampicin-based short course chemotherapy gives satisfactory results<sup>18</sup>. **This study also shows that the RNTCP policy in India of treating all re-treatment cases with the WHO recommended re-treatment regimen may be adequate except for the MDR-TB patients. DST should be done for patients who remain sputum smear positive during the re-treatment period and appropriate regimens should be started as early as possible for better treatment outcome and to reduce transmission of drug resistant TB.** Of the patients who remained sputum smear-positive at the end of 3 and 4 months of treatment, 23% and 41% respectively had MDR-TB. Among the patients who failed to CAT-II regimen, 32% had MDR-TB. The limitations of this report are high default rate and DST could not be done for a significant number of cases who remained smear positive during treatment. However, the initial drug susceptibility profile was similar among patients for whom sputum was not collected to those from whom sputum was collected. The results are from a localized area and

need to be confirmed from other areas as well.

## CONCLUSION

**The low success rate to the CAT-II regimen was mainly due to the high default during treatment. If treatment compliance can be ensured for all patients majority of patients registered to CAT-II regimen can have a successful treatment outcome. Development of resistance to Rifampicin observed among failures to CAT II regimen was low. A high proportion of patients who failed to CAT-II regimen had either susceptible or resistant but non-MDR bacilli. The high default rate observed in the study area suggests the need for enhanced counselling and supervision with targeted health education.**

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## PRIVATE SECTOR INVOLVEMENT IN TUBERCULOSIS CONTROL IN CHANDIGARH

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### Summary

**Background:** Private practitioners in India treat a substantial proportion of the TB cases. The present study is an attempt to find out the extent of private sector involvement in the control of tuberculosis in the Union Territory of Chandigarh.

**Methodology:** The study was conducted in Union Territory of Chandigarh, during 2003-04. This study was a cross-sectional study involving 20 per cent of private practitioners practising allopathic system of medicine in Chandigarh. A questionnaire was used for collection of data after pre-testing.

**Results:** Out of 114 doctors interviewed, 71 per cent dealt with TB patients. In response to a question as to how many sputum samples were required for routine microscopy, 72 per cent stated 3 samples but only 6 per cent knew the correct timing of sputum collection. 8.6 per cent of the practitioners followed the recommended guidelines of RNTCP treatment. As to reasons for not following the standard guidelines, 46.6 per cent said that they were not aware of these guidelines. About 82 per cent were willing to be partners for implementation of RNTCP. A case history was given to practitioners to assess their knowledge regarding DOTS. It was observed that only 7.8 per cent knew the correct dosage and 21 per cent knew the correct duration of treatment.

**Conclusion:** Knowledge of private practitioners regarding RNTCP and DOTS strategy was poor and they were not following recommended guidelines for control of tuberculosis, but they were willing to participate in the programme. [*Indian J Tuberc* 2006; 53:149-153]

**Key Words:** Tuberculosis, Private practitioner, Knowledge, RNTCP, TB.

### INTRODUCTION

The private sector accounts for 82 per cent of all out patient visits at the all India level, with no significant variations by income group<sup>1</sup>. Suspected TB patients also first approach private sector. Private practitioners in India treat over half of the TB cases<sup>2</sup>. In many parts of India, the private sector has still remained alienated from DOTS implementation; hence case detection has remained low in many of these regions. Unfortunately, case management practices in the private sector overly rely on X-ray and treatments too often are based on unproved and untested regimens<sup>2</sup>.

For national programme to broaden its reach and have maximal impact, the involvement of private practitioners assumes great importance. It is one of the big challenges to policy makers in India to ensure their participation, which is intimately linked with

the success of the programme. Hence, present study is an attempt to observe the extent of the private sector involvement in implementation of Revised National Tuberculosis Control Programme (RNTCP) in the Union Territory of Chandigarh.

### MATERIAL AND METHODS

The study was done in the Union Territory of Chandigarh during the year 2003 - 04. This was a cross-sectional study involving 20% of the private practitioners, who are practising allopathic system of medicine in Chandigarh. Since the data about the involvement of private practitioners in RNTCP for Chandigarh was not available when the study was planned, a sample of 20% practitioners was taken randomly for further study. A list of all doctors practising in allopathic system of medicine was obtained from the Indian Medical Association (IMA), Chandigarh branch. A questionnaire was used after

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pre-testing. The questionnaire had two parts – information on management of tuberculosis and the other on case history. The first part sought information regarding methods of diagnosis, how many samples of sputum are required, knowledge on treatment categories and any training received under RNTCP, provision of treatment under supervision, reasons for not following recommended guidelines and if given an opportunity would they like to be a partner for implementation of RNTCP. The second part on case history was to assess their knowledge regarding treatment protocol and drug dosage of anti-tubercular therapy under the RNTCP guidelines and the authenticity of the information provided.

A field worker visited a private practitioner with prior appointment. After taking his/her consent, he gave the questionnaire to collect the relevant information. A case history was given to each practitioner to assess his or her current management practices and check the authenticity of the information provided. The history was about a 35-year old male, weighing 60 kg, with a 3 weeks' history of cough with expectoration and mild fever, positive history of contact with a TB case. The chest X-ray showed hilar lymphadenopathy with consolidation of medial basal segment. The doctor put this patient on ATT with HRZE drugs. Questions pertaining to management of that case were put forth.

The data was entered into a computer for further analysis. Statistical analysis was done by using Epi info 2000. Proportions of different variables were calculated and compared.

## RESULTS

Out of 114 doctors interviewed, 59.6% were males and 40.4% females. About one fourth (24%) were doing private practice for less than 5 years, 25% for 5-10 years and 51% for more than 10 years. The profile of respondents is given in Table 1. Of all, 71% dealt with TB patients in their routine practice. Only 8.6% registered tuberculosis patients and send this information to District Tuberculosis Centre. About 95% doctors stated that they did not have any TB patients registered with them at the

time of interview.

About 29 (35%) practitioners dealing with TB patients, have their own laboratory facilities for diagnosis of TB patients. Out of them, 55% had X-ray facilities and 45% had laboratory facility to do sputum examination for acid-fast bacilli (AFB). Out of 52 (65%) practitioners who do not have laboratory facilities in their clinic, 73% send tuberculosis patients to private laboratories for diagnosis, 17% send them to District Tuberculosis Centre for diagnosis and only 3% send them to nearest government hospital. About 72% stated that 3 sputum samples should be taken routinely for sputum microscopy, but only 6% told the correct timing of sputum collection i.e. spot - morning - spot. The response of the private practitioners about the diagnosis of tuberculosis patients is given in Table 2.

In response to how to diagnose a case of tuberculosis, 40% of the practitioners said that X-ray was their first priority for diagnosis. Majority (65%) of practitioners said X-ray and single sputum positive for AFB is required for confirmation of the disease. Only 2% said that 2 samples of sputum positive for (AFB) were needed for confirmation of tuberculosis. Only about one third (33%) said the name for national programme for tuberculosis as Revised National Tuberculosis Control Programme

**Table 1:** Profile of selected private practitioners in Union Territory of Chandigarh

Variables	No (n=114)	Percentages
<b>Sex distribution</b>		
Male	68	59.6
Female	46	40.4
<b>Qualification</b>		
MBBS	31	27.2
MD	56	49.2
Others (Additional degree*)	27	23.6
<b>Years of private practice</b>		
< 5 years	27	23.6
6 – 10 years	28	24.7
> 10 years	59	51.7

\*DM, DNB, FRCP, etc.

(RNTCP). About 17% of the participants had received training under National Tuberculosis Programme. Out of this 17% received training under RNTCP, 50% followed these guidelines for treatment. While comparing with total population of private practitioners who deal with TB patients, only 8.6% followed the recommended RNTCP guidelines. About 11% practitioners said that they knew about various treatment categories under RNTCP but only 4% could specify three categories. The knowledge of private practitioners regarding management of tuberculosis cases is given in Table 2.

Only 15% of the private practitioners provide supervised treatment to TB patients, and the treatment was provided by the practitioner himself (50%), family members (33%) and the clinic staff (17%). About the reasons for not following the national TB treatment guidelines, 47% said that they were not aware and 10% said that they thought that the guidelines were only for government doctors.

About 69% strongly agreed, 30% agreed and only 1% strongly disagreed that involvement of private practitioners is important for control of TB in India. About 82% of private practitioners expressed their willingness to be partners for implementation of national TB control programme.

**Table 2:** Knowledge of private practitioners regarding management of Tuberculosis cases.

Parameters	No (n = 81)	Percentages
Three sputum samples	59	72.8
Correct method (spot-morning-spot)	05	6.2
Name of National programme	38	46.9
Received training under RNTCP	14	17.2
Following RNTCP guidelines	07	8.6
Treatment categories	03	3.7
Supervised treatment	12	14.8

An open-ended question was asked on how the involvement of private practitioner could be ensured in RNTCP. They felt that regular training of private practitioners on national TB guidelines and incentives should be given to private practitioners after completion of treatment of TB patients.

A case history was given to them to assess management practices and to test the authenticity of the answers they had provided. About 94% of the practitioners said that the patient should have been investigated further and 63% agreed with the therapy provided. Only 7.8% knew the correct dosage of Rifampicin, Isoniazide, Pyrazinamide and Ethambutol and 21% knew the correct duration of treatment.

## DISCUSSION

The RNTCP is being primarily implemented through the Government network of institutions and health providers. Several studies have suggested that roughly 50% of the population sought medical care from the Private Sector in India<sup>2,3</sup>. This aspect needs further research as to why patients prefer to go to private practitioners first. The RNTCP, therefore, cannot hope to achieve major successes unless public-private mix is a success.

It was found in the present study that only 8% of the private practitioners send the information to District Tuberculosis Centre. This finding is consistent with the finding of a study from Pakistan where this rate was 6% and another study further pointed out that private practitioners rarely report TB cases to the relevant national health authorities and are generally not involved in national TB control programmes<sup>4,5</sup>. About 20% of the private practitioners send their patients for diagnosis to district tuberculosis centre and nearest government hospitals.

Still, 40% of the practitioners in Chandigarh stated that X-ray was their first priority for diagnosis while 65% said X-ray and single sputum specimen positive for AFB were required for confirmation of the disease. This is less than the 75% shown by another study<sup>6</sup>. Two thirds of practitioners had no idea about the name of the national programme for

tuberculosis in India. A merely 3% knew about the three treatment categories in tuberculosis management. This indicates the poor level of awareness among the practitioners.

The majority (88.4%) of private practitioners were not aware of, or were not prescribing the treatment regimen recommended by the RNTCP. This finding is substantiated by various studies in India<sup>7,8</sup>. A study in Maharashtra found that many private doctors prescribe wrong TB drugs and they were not providing supervised treatment<sup>8,9</sup>. A study conducted in Delhi had demonstrated that only 29.4% of the private practitioners were using the regimen recommended by the RNTCP<sup>7</sup>. Only 7.8% knew the correct dosage combination of anti-tubercular treatment. This indicates that they are prescribing inappropriate treatment regimens for management of tuberculosis patient. A study in Maharashtra showed that 100 private doctors prescribed 80 different regimens, most of which were both inappropriate and expensive<sup>8</sup>.

A study has shown that many reasons could be attributed to the diagnostic delay and improper management of tuberculosis patients in the private sector<sup>10</sup>. These were lack of awareness of recommended best practice, due to outdated information sources, and lack of access to reliable and up to date evidence; increased likelihood of private practitioners to be working alone along with promotional literature from pharmaceutical companies. These results also substantiate many of our findings.

Majority of private practitioners are not aware of or not prescribing the treatment regimen recommended by the RNTCP and the majority of patients are being improperly treated or over-treated. There is a lack of emphasis on proper supervised treatment provision. They need periodic training, and more collaborative efforts are required between public health facilities and practising doctors for control of tuberculosis. It was observed that half of the practitioners who had received training were following RNTCP guidelines as compared to 8.6% of those who did not receive training. Anti-tubercular

drugs can be provided through the private practitioners after imparting necessary training to them. District Tuberculosis Centre should also develop partnership with local NGOs. This could be achieved by extending public private mix (PPM) under RNTCP to more areas and its effective implementation as per local needs.

Although the study revealed gaps and weaknesses in the private doctors reported practice of managing tuberculosis, it was observed that majority of the private practitioners wanted to be a part of RNTCP. This willingness could be utilized properly for building public private partnership for control of tuberculosis in Chandigarh.

### Impact on Policy Makers

After the study, a dialogue was established with the State Tuberculosis Officer (STO), Chandigarh. Since RNTCP was implemented in Chandigarh from January 2002, and the study was conducted in 2003, it was not expected that there would be a substantial change in attitude / participation of private practitioners. However, after discussion with State Tuberculosis Officer, training sessions were organized for the private practitioners. The initial response after training has been found to be very encouraging. Till 31<sup>st</sup> March 2005, 131 private practitioners have been involved in tuberculosis control in Chandigarh.

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**STATUS REPORT ON RNTCP\***

**India achieves nation wide coverage under DOTS in 1<sup>st</sup> quarter 2006**

Revised National Tuberculosis Control Programme has covered the entire population of the country on the eve of 24<sup>th</sup> March 2006 – World TB Day. The RNTCP was implemented in a population of 2.35 million in 5 pilot sites (Gulabi Bagh, Delhi; Pathanamthitta, Kerala; Mehasana, Gujarat; BMC, Maharashtra; Calcutta, West Bengal in 1993, and currently extends to all the 632 districts/reporting units covering 1114 million population.

**Performance**

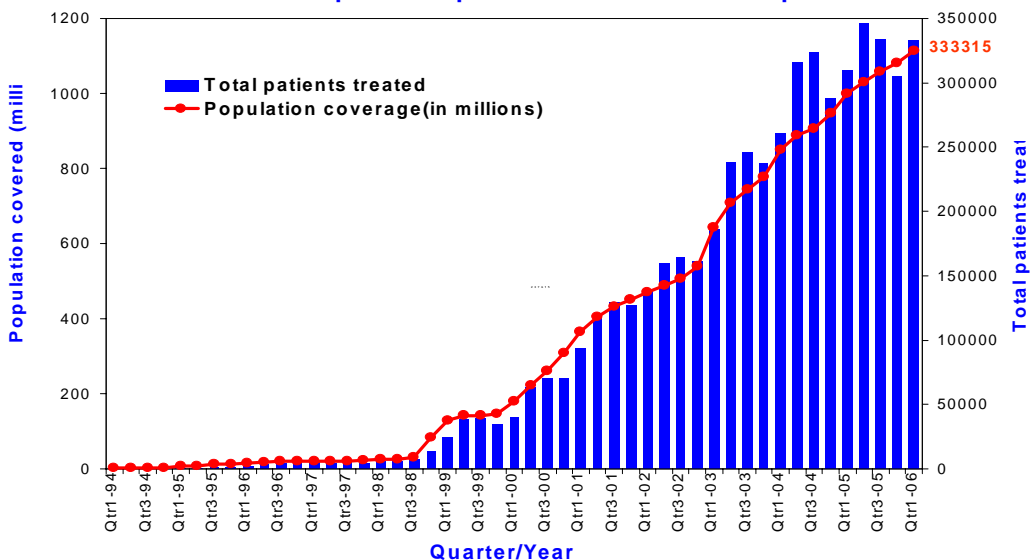
The case detection rate for the 1<sup>st</sup> quarter of 2006 was 63% with a total of 331,525 patients placed on treatment. This is low as compared to the NSP CDR of 66% in 1q05. Some of the large states viz. Andhra Pradesh, Bihar, Karnataka, Kerala, Maharashtra, Madhya Pradesh, Orissa and Tamil

Nadu have shown decline. This is a matter of concern for the programme and detailed district and TU wise analysis to identify the reasons for the same is being undertaken.

Over 15 lakh suspects were examined during the quarter and 1.9 lakh sputum positive cases were diagnosed. In addition to the 129,083 new smear positive cases, 98,678 new smear negative cases, 45,064 extra pulmonary cases, and 44,146 smear positive re-treatment cases were also initiated on treatment in this quarter. The extra-pulmonary TB cases accounts for 17% of all new cases in the quarter and re-treatment cases for 25% of all smear positive cases.

The success rate amongst the new smear positive PTB cases registered in the 1<sup>st</sup> quarter of

**Population in India covered under DOTS and total tuberculosis patients put on treatment each quarter**



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**Table:** Performance of RNTCP Case Detection (2006, first quarter), Smear Conversion (2005, fourth quarter), and Treatment Outcomes (2005, first quarter)

State	Population (in lakh) covered by RNTCP <sup>1</sup>	Suspects examined per lakh population	No of Smear positive patients diagnosed <sup>2</sup>	Total patients registered for treatment <sup>3</sup>	Annualized total case detection rate	New smear positive patients registered for treatment	Annualized new smear positive case detection rate (%)	3 month conversion rate of new smear positive patients <sup>4</sup>	Cure rate of new smear positive patients <sup>5</sup>	Success rate of new smear positive patients <sup>5</sup>	No of new smear negative cases registered for treatment	No of new EP cases registered for treatment	No of smear positive re-treatment cases registered for treatment
Andaman & Nicobar	4	255	79	221	224	57	58 (77%)	89%			75	62	16
Andhra Pradesh	804	134	15425	26404	131	10159	51 (67%)	90%	85%	88%	9578	2422	3356
Arunachal Pradesh	12	221	359	577	197	217	74 (99%)	94%	86%	88%	159	55	104
Assam	290	84	3926	6893	95	2873	40 (53%)	85%	77%	81%	2169	599	780
Bihar	903	45	5206	10845	64	3183	19 (25%)	81%	81%	85%	5180	455	1212
Chandigarh	10	385	386	523	207	168	66 (70%)	95%	83%	83%	101	150	60
Chhatisgarh	229	114	3206	6742	118	2545	45 (56%)	88%	81%	84%	2779	716	458
D & N Haveli	2	183	55	95	153	48	77 (97%)	80%			21	17	8
Daman & Diu	1.8	451	48	43	97	17	38 (48%)	95%			15	5	6
Delhi	161	271	6609	12380	308	3478	87 (91%)	90%	86%	86%	2483	3679	1683
Goa	15	173	243	447	116	148	39 (48%)	87%	73%	73%	137	92	44
Gujarat	548	165	14355	19836	145	7937	58 (72%)	91%	85%	86%	3471	2490	4200
Haryana	230	171	5352	8004	139	2887	50 (53%)	89%	82%	83%	1817	1122	1675
Himachal Pradesh	64	258	2149	3255	203	1250	78 (82%)	92%	88%	89%	568	654	660
Jammu & Kashmir	116	143	1011	2396	83	801	28 (29%)	87%	77%	83%	650	651	202
Jharkhand	292	82	3659	7377	101	2791	38 (51%)	83%	77%	88%	3114	426	587
Karnataka	561	159	9828	16129	115	6189	44 (59%)	86%	80%	81%	3959	2993	2142
Kerala	336	191	3660	6345	76	2727	32 (43%)	86%	83%	86%	1438	1429	573
Lakshadweep	0.7	71	2	9	55	2	12 (16%)				5	2	0
Madhya Pradesh	668	96	10772	17605	105	6600	40 (49%)	87%	79%	82%	5810	1729	2681
Maharashtra	1041	142	18707	35134	135	13454	52 (65%)	91%	86%	87%	10354	5337	3704
Manipur	26	132	346	1131	177	271	42 (56%)	90%	85%	85%	383	202	84
Meghalaya	25	112	457	901	146	311	50 (67%)	87%	77%	79%	188	164	136
Mizoram	10	209	207	467	196	153	64 (85%)	95%	88%	88%	104	139	46
Nagaland	21	108	241	633	119	209	39 (52%)	91%	86%	87%	149	130	80
Orissa	391	114	6009	10447	107	4474	46 (54%)	86%	77%	85%	2963	1684	800
Pondicherry	10	387	366	431	165	171	66 (88%)	84%	68%	71%	109	79	65
Punjab	260	159	5086	8188	126	3261	50 (53%)	87%	79%	84%	1980	1482	1192
Rajasthan	624	139	15628	24221	155	8663	56 (69%)	91%	86%	87%	7357	2798	4649
Sikkim	6	298	204	346	239	126	87 (116%)	93%	85%	85%	50	85	64
Tamil Nadu	653	259	13154	23244	142	8748	54 (71%)	88%	83%	85%	6879	4734	2253
Tripura	34	80	329	493	58	265	31 (41%)	88%	81%	86%	86	61	65
Uttar Pradesh	1839	122	31318	51512	112	21560	47 (49%)	90%	84%	87%	17067	4490	7255
Uttaranchal	92	160	1832	2695	117	983	43 (45%)	94%	87%	88%	810	331	503
West Bengal	858	177	16797	27346	128	12357	58 (77%)	90%	86%	87%	6670	3600	2803
<b>Grand Total</b>	<b>11136</b>	<b>140</b>	<b>197011</b>	<b>333315</b>	<b>123</b>	<b>129083</b>	<b>48 (63%)</b>	<b>89%</b>	<b>83%</b>	<b>86%</b>	<b>98678</b>	<b>45064</b>	<b>44146</b>

1. Projected population based on census population of 2001 is used for calculation of case-detection rate. 1 lakh = 100,000 population

2. Smear positive patients diagnosed include new smear positive cases and smear positive retreatment cases

3. Total patients registered for treatment includes new sputum smear positive cases, new smear negative cases, new extra-pulmonary cases, smear positive retreatment cases and 'Others'

4. Smear conversion rate not expected for states that began implementing RNTCP during 4th quarter 2005

5. Cure rate and success rate are not expected for states that began implementing RNTCP after 4th quarter 2004

2005 was 86%. The sputum conversion rate and cure rate among the new sputum positive cases was 89% and 83% respectively.

### ***External Quality Assessment (EQA) implementation***

The training of state level trainers on the Sputum Microscopy EQA protocol have been completed for all states and union territories at the national level at TRC, Chennai and NTI, Bangalore. All RNTCP consultants are also trained on EQA. Training of DTOs and district level staff on EQA has been completed in more than 24 States and are underway in other States. However, more than 400 of 601 districts, implementing the program in 4<sup>th</sup> qtr 05, have not reported their EQA activities in the current quarter. EQA activities have been planned so as to augment the quality of smear microscopy services. All districts are requested to complete EQA implementation and ensure complete and correct reporting of EQA activities in future.

### ***Activities in 1<sup>st</sup> quarter 2006***

*Biannual STO and Consultants meeting:* National level meeting of the State TB Officers and

RNTCP Consultants from Zone II (includes southern and north-eastern states) was organized to review the performance and programme related issues in these states under Phase II of RNTCP. The states have been asked to strengthen supervision and monitoring at all levels, follow up EQA implementation, review TB HIV collaboration and training activities in order to maintain the highest quality of service delivery.

*TB Prevalence survey:* An expert group meeting was convened to discuss the issues pertaining to conducting TB prevalence surveys in the country. TB disease prevalence survey at select sites was proposed to obtain information on impact of RNTCP on TB prevalence and measure progress of India towards MDG goal of halving the prevalence of TB by 2015. A generic protocol was developed and agreed upon for conducting the survey at the identified sites.

*World TB Day* was observed across the country, and was marked by organizing symbolic run for TB, symposia and workshops. At the national level, Hon'ble Health Minister flagged off the run and released the RNTCP Annual Report 'TB India 2006' on the occasion.

## Case Report

# ACUTE RESPIRATORY DISTRESS SYNDROME AS A PARADOXICAL RESPONSE TO ANTI-TUBERCULOSIS AND ANTI-RETROVIRAL THERAPY

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(Original received on 25.10.2005; Revised version received on 2.4.2006; Accepted on 13.4.2006)

**Summary:** Paradoxical response or immune reconstitution inflammatory syndrome (IRIS) during the course of anti-tuberculous therapy is being increasingly recognised among patients with and without HIV co-infection. A 40-year-old HIV infected male on anti-retroviral therapy (ART) presented with persistent fever and weight loss. He was diagnosed to have miliary tuberculosis and HIV co-infection. Following initiation of anti-tuberculous chemotherapy, the clinical course was characterised by development of acute respiratory failure (ARDS) as a paradoxical response/IRIS to treatment. This uncommon manifestation of paradoxical response (ARDS) in HIV and tuberculous co-infection following initiation of ART and anti-TB treatment is very scarcely reported in the past. With the increasing incidence of HIV/AIDS and TB co-infection along with liberal access to ART in the developing world, it is likely that paradoxical reactions will be encountered more frequently. [*Indian J Tuberc* 2006; 53:157-160]

**Key words:** Tuberculosis, AIDS, ARDS, Paradoxical response, IRIS, ART, HAART.

## INTRODUCTION

Paradoxical worsening of tuberculosis symptoms in response to initiation of anti-tuberculous therapy is well recognised for many years in non-HIV infected individuals<sup>1,2</sup>. The most common of such paradoxical response is worsening of fever and development of new or increase in size of already existing lymph nodes in both HIV infected and non-infected individuals<sup>3,4</sup>. Over the past few years, paradoxical response, also called as immune reconstitution syndrome (IRS) or immune reconstitution inflammatory syndrome (IRIS) is more frequently noted in patients co-infected with HIV and tuberculosis especially after the introduction of highly active anti-retroviral therapy (HAART)<sup>5-10</sup>. Acute respiratory distress syndrome (ARDS) manifesting as a paradoxical response to initiation of anti-TB medication is very rarely noted in patients with pulmonary tuberculosis<sup>2</sup>. However, in miliary tuberculosis, it is well known to occur among non-HIV infected patients and there are numerous publications on this aspect in the literature<sup>11-13</sup>. Acute respiratory distress syndrome as a manifestation of

IRIS in HIV infected tuberculosis patients is not well described and there are only occasional reports of this condition in the literature<sup>14,15</sup>. Here we report a paradoxical response/IRIS presenting as ARDS following initiation of anti-TB and HAART treatment in an HIV infected TB patient. We have also made an attempt to briefly review IRIS in HIV and tuberculosis co-infection in this article.

## CASE REPORT

A 40-year old man was diagnosed to have HIV infection in a community hospital when he presented with complaints of low-grade intermittent fever, mild productive cough and significant weight loss over 4 months. He was referred to our centre six weeks after initiation of treatment with anti-retroviral (ART) drugs consisting of Zidovudine 600 mg a day, Lamivudine 300 mg a day and Nevirapine 400 mg daily for evaluation of persisting fever and weight loss.

Physical examination revealed a thinly built individual with significant pallor but otherwise

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**Fig 1:** Frontal radiograph of the chest showing bilateral reticulo nodular infiltrates suggestive of miliary tuberculosis.



**Fig 2:** Frontal radiograph of the chest showing bilateral fluffy alveolar opacity suggestive of ARDS

unremarkable systemic examination. Investigations revealed hemoglobin of 7.8 gm/dl and total leukocyte count of 2,300 cells/cu mm. Liver function showed total bilirubin 1.2 mg %, direct bilirubin 0.7 mg%, total protein 8.5 gm%, albumin 2.4 g%, SGOT 142 U/L, SGPT 54 U/L, alkaline phosphatase 862 U/L. Electrolytes and serum creatinine were normal. HIV antibody was positive by ELISA test. HbsAg and VDRL were negative. Blood cultures and smear for malarial parasites were negative. Three consecutive morning samples of sputum were negative for AFB. Chest radiograph (Fig.1) showed diffuse miliary nodules bilaterally suggestive of miliary tuberculosis. Bone marrow biopsy showed evidence of granulomatous infiltration consistent with tuberculosis. Subsequently, bone marrow culture grew two colonies of morphologically typical *Mycobacterium tuberculosis*.

A diagnosis of disseminated tuberculosis was considered and the patient was initiated on standard anti-TB regimen consisting of Isoniazid 300mg daily, Rifampicin 450mg daily, Pyrazinamide 1.5g daily and Ethambutol 800mg daily. Cotrimoxazole was given for *Pneumocystis carinii* pneumonia prophylaxis. While he was in the hospital awaiting further evaluation of CD<sub>4</sub> cell count and HIV viral RNA load, he developed sudden onset of dyspnoea, tachypnea, cyanosis and bilateral

crepitations on the third day after initiation of anti-tuberculous treatment. An arterial blood gas showed severe hypoxemia with a PaO<sub>2</sub> of 35 mm Hg and PaCO<sub>2</sub> of 19 mm Hg on breathing room air. Chest radiograph (Fig. 2) showed extensive bilateral fluffy alveolar shadows suggestive of acute respiratory distress syndrome (ARDS). Despite supplementary O<sub>2</sub> therapy and resuscitation measures he progressively worsened and died within a few hours.

## DISCUSSION

Paradoxical response to tuberculosis treatment is well known to occur in both HIV and non-HIV infected individuals<sup>4</sup>. Various manifestations of paradoxical response are described, such as worsening fever, development of new or increase in size of already existing lymph nodes and enlargement of cerebral tuberculomas, *etc.*<sup>1,3,6</sup>. Paradoxical response during the course of treatment is attributed to an immunological consequence of drug therapy precipitated by highly immunogenic cell-wall products/antigens of the mycobacterium being released during the course of bactericidal chemotherapy<sup>2</sup>.

Paradoxical worsening of pulmonary lesions, leading to respiratory failure, although rare, are more commonly noted in miliary tuberculosis

than in non-miliary pulmonary tuberculosis among patients without HIV infection<sup>11-13</sup>. They are associated with high fatality when it occurs in miliary TB<sup>11</sup>. Respiratory failure in miliary tuberculosis is postulated to be secondary to extensive pulmonary involvement and also due to a hypersensitivity reaction following initiation of bactericidal anti-TB chemotherapy. In turn, this leads to damage of the alveolar-capillary membrane leading to increased permeability resulting in respiratory failure (ARDS)<sup>2</sup>.

Paradoxical response or immune reconstitution inflammatory syndrome (IRIS) is more frequently recognised in patients co-infected with tuberculosis and HIV, especially among those who are initiated on combination ART<sup>5-7</sup>. This is thought to be related to host immune restoration in the presence of mycobacterial antigen during the course of ART therapy<sup>5,7</sup>. This manifests usually four to ten weeks after initiation of ART, more frequently noted with extrapulmonary and disseminated TB<sup>16</sup>, generally self-limiting, last for about 10 to 14 days<sup>5,10</sup>. It is also noted that patients who develop tuberculosis 1-4 months after starting ART are more prone to develop significant IRIS compared to those who develop TB later<sup>17</sup>. Acute respiratory distress syndrome manifesting as IRIS in HIV and tuberculosis co-infection is extremely rare and there are only a few reports of this condition in the literature<sup>14,15</sup>. Earlier published reports suggest that IRIS coincides with starting of ART among HIV infected TB patients who are already on anti-TB therapy (anti TB followed by anti-retroviral therapy)<sup>1</sup>. The patient presented here was on anti-retroviral therapy for a period of one and half months prior to our initiating him on anti-TB drugs. He developed the IRIS within a span of three days after the initiation of anti-TB therapy (anti retroviral followed by anti-TB). It is reasonable to assume that in this patient the paradoxical response was related to exposure to mycobacterial antigens following bactericidal TB chemotherapy in the presence of heightened immunity. The explosive nature of the response in this patient was probably related to the immune reconstitution related to the prior ART.

Though the patient presented here had definitive evidence of disseminated tuberculosis, we

were unable to exclude other concomitant infections because of the rapid worsening of the acute illness, such as *Pneumocystis carinii* pneumonia and other uncommon infections, which can present with respiratory failure in the background of HIV infection even though he was on co-trimoxazole prophylaxis.

**This case is presented to highlight that IRIS can manifest as ARDS in HIV infected individuals who are initiated on anti-TB treatment and ART. With the increasing incidence of HIV/AIDS and TB co-infection in developing world along with liberal access to ART for these individuals, it is likely that IRIS will be encountered more frequently in atypical forms. However, other concomitant conditions need to be excluded. Failure to recognise ARDS secondary to IRIS may lead to provisional therapy for other more common pulmonary conditions and other opportunistic infections<sup>14</sup>. Moreover, in anecdotal case reports, mechanical ventilation and corticosteroids are shown to be helpful<sup>14</sup>. However, the usefulness of these interventions in HIV infected individuals presenting with this condition need to be studied further.**

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## Case Report

# TUBERCULOSIS IN PILONIDAL SINUS

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(Original received on 6.3.2006; Revised Version received on 24.4.2006; Accepted on 2.5.2006)

**Summary:** Pyogenic infection occurring in the pilonidal sinus is very common in young individuals with sedentary occupation. Tuberculous infection of pilonidal sinus is extremely rare and restricted to a case report in the literature. We present a 68-year-old male presenting with long standing pilonidal sinus with tuberculous infection [Indian J Tuberc 2006; 53:161-162]

**Key Words:** Pilonidal Sinus, TB infection, granuloma.

## INTRODUCTION

Tuberculosis is endemic in South Asian countries. With the advent of pandemic of acquired immuno-deficiency disease, tuberculosis is spreading even in the western population. Tuberculosis has been found at rare sites as exemplified by its rare occurrence in pilonidal sinus<sup>1</sup>.

## CASE REPORT

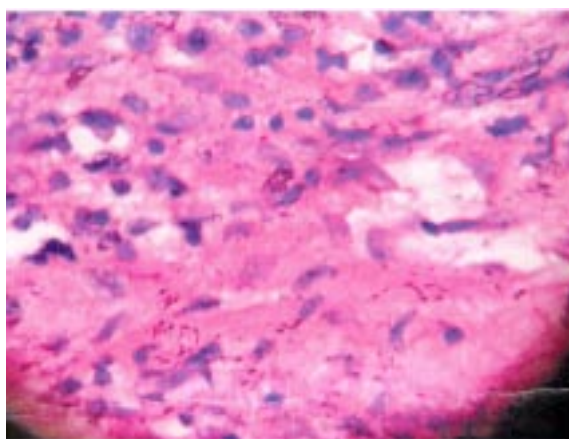
A 68 year old obese businessman presented with a sinus in the intergluteal cleft with a nest of hair within. Surrounding skin was normal. Clinical diagnosis of pilonidal sinus was made. X-ray lumbosacral spine was normal. Wide excision of the sinus was done. Sinus was extending till the subcutaneous tissue. Primary closure of the skin was not possible due to a large raw surface area. Post-operative recovery was uneventful. Histopathology of the specimen on Hematoxylin and Eosin stain revealed skin covered tissue with pilosebaceous unit and sweat glands. Deep dermis showed many calcified deposits, a few epithelioid granulomas with caseation in centre with Langhans' giant cells suggestive of calcified tuberculosis (Fig.). Tissue for Acid Fast Bacilli staining was negative. No malignancy was detected. Patient was started on four drug anti-tuberculosis therapy. Follow up after 5 months

showed wound healed with no recurrence.

## DISCUSSION

Pilonidal sinus is subcutaneous tract with tuft of hair within, occurring in late teens and adult life. Commonest mode of presentation is chronic discharging sinus, especially in patients having sedentary occupation<sup>2,3</sup>.

Pilonidal sinus commonly gets secondarily infected. Infection by pyogenic organisms is the commonest<sup>4</sup>. Infection by other rare organisms are



**Fig.:** H and E stain showing tuberculous epithelioid granuloma.

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also noticed and are restricted to the case reports in literature. Chikkamuniyappa S *et al* reported three cases of pilonidal sinus with actinomyces<sup>5</sup>. Jamil *et al*<sup>1</sup> reported a solitary case of tuberculous infection of pilonidal sinus. This case was similar to ours as the morphology was that of routine pilonidal sinus and tuberculosis was detected only on histology. **The reviewers here thus stress, as we do, the necessity of sending all specimens for histological examination. This is especially true in our country where tuberculosis is common. In our case, though AFB staining was negative, other findings on histopathology were sufficiently indicative of tuberculosis. Anti-tuberculous chemotherapy is essential for complete treatment of these patients as exemplified by good healing and overall**

**recovery of our patient.**

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**SUMMARIES OF PAPERS PRESENTED AT THE 60TH NATIONAL CONFERENCE ON TUBERCULOSIS AND CHEST DISEASES HELD IN LUCKNOW, FEBRUARY 23-26, 2006.**

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**A five-year follow-up study of RNTCP in Lucknow**

*S.K. Verma, Rajendra Prasad, Surya Kant, Santosh Kumar and Sanjay Kumar Verma.*

**Objective:** To determinate the post-treatment status of the tuberculosis patients who had been registered under RNTCP during October 1998 to October 1999.

**Setting:** DOTS Centre Unit C-9 KGMU, Department of Pulmonary Medicine, Lucknow.

**Study period:** August 2004 To August 2005.

**Method:** All the 208 patients of Tuberculosis were followed-up in their homes, door to door, with the help of RNTCP personnel and evaluated in the form of pre-designed format.

**Observation:** Outcome of all the 208 patients, after completion of their DOTS treatment was: Treatment success (cured+ TC) - 187(89.90%), Defaulter - 11 (5.28%), Died - 9 (4.32%), Failure - 1 (0.48%).

Follow-up result after a gap of 5-year showed that only 80(38.14%) patients were found. While 73(35.06%) patients were not present because of migration to some other place, 46(22.11%) addresses could not be traced. The follow-up of 80 patients revealed Asymptomatic 73(91.25%). Only two relapses were found, one in CAT-I and one in CAT-II and 5 died.

**Conclusion:** Treatment under DOTS is effective.

**Post ATT status of Category II patients under RNTCP**

*K. Thirupathi, Atharunnisa Begum and A.Devarajan*

**Objective:** The object of the study was to evaluate

the present status of the patients who received category II anti-tuberculous treatment three years ago.

**Type of Study:** Retrospective Cohort Study

**Methodology:** The study was conducted by Institute of Thoracic Medicine, Chetpet, MMC, Chennai during the year 2005. The study group included the patients who had category II anti-tuberculous treatment in the Tuberculous units 3, 7 and 9 of Chennai Corporation under RNTCP in the year 2002. The patients were traced using tuberculosis register; patients were traced using post cards and by person. Clinical, bacteriological and radiological status of the patients were studied.

**Findings:** About 142 patients were registered for category II in the year 2002 in the 3 TB units of Chennai Corporation. Among them, 30 patients were found to have already expired. Thirty-eight patients could not be traced either because of incomplete address or migration. The analysis of remaining 74 patients were presented.

**Conclusion:** Out of 142 patients registered, 21% of patients died. Of the 21% died, 10.5% during treatment and 10.5% afterwards. This increased death rate is really a cause of concern.

**Comparison of bronchoalveolar lavage fluid with sputum culture in the diagnosis of sputum smear negative pulmonary tuberculosis.**

*Naveed Nazir Shah, Arshad Altaf Bachh, Rakesh Bhargava, Zuber Ahmed, D.K. Pandey and Mohd. Shameem.*

**Aim:** To assess the role of bronchoalveolar lavage (BAL) fluid culture in comparison with sputum culture for making bacteriological diagnosis.

**Material and Methods:** The study was conducted

on patients attending OPD/IPD Department of Tuberculosis and Chest Diseases, JNMCH, AMU, Aligarh. Twenty patients presenting with symptoms suggestive of pulmonary tuberculosis with at least six sputum smear negative results for acid fast bacilli (AFB) but with radiographic appearances suggestive of pulmonary tuberculosis were evaluated by sputum and BAL culture for the demonstration of *M. tuberculosis*. Sputum smears were stained by the Z.N. stain. The BAL specimens were inoculated on Lowenstein Jensen (LJ) medium.

**Results:** Of the 20 patients, 9 had positive cultures of *M. tuberculosis* from sputum. Of them, 6 (66%) had both sputum and BAL fluid cultures positive for *M. tuberculosis* and in none was BAL fluid positive without sputum being positive. Thus, the yield from BAL fluid was only 66% of that by sputum culture examination. In only 2 patients, was BAL smear positive and in these patients sputum and BAL cultures were also positive.

**Conclusion:** The results of this study indicate that a single bronchoscopic procedure such as bronchoalveolar lavage fluid culture may not be superior to sputum culture examination.

#### Value of sputum smear examination in diagnosing tuberculosis even in tertiary care centre

*G.R.Sridhar, R. Atharunnisa Begum and B. Rajagopalan*

**Objective:** Importance of sputum smear examination in diagnosing tuberculosis even in places like tertiary care centre where chest radiography is freely available

**Methodology:** All the patients attending the Institute of Thoracic Medicine, Chennai, for the first time in outpatient department and the patients referred from private practitioner with chest radiography alone were included. The referred patients with chest radiography from private practitioners were diagnosed by them as Pulmonary Tuberculosis. All these patients were subjected to sputum smear examination as per the RNTCP guidelines. The chest radiography of all patients were screened and

categorised into Minimal, Moderately advanced and Far advanced tuberculosis as per the American Thoracic Society guidelines. Patients with Diabetes and HIV positive were not included in this study. The results of chest radiographs and sputum smear examination of each patient were analysed and correlated.

**Findings:** The study analysis showed, there is good correlation between the smear reports and radiological extent of the disease. But there is also a good number of radiological abnormalities diagnosed as pulmonary tuberculosis by private practitioners found to be smear negative and proved to be non-tuberculous lesion.

**Conclusion:** This study again proves the importance of sputum smear examination even in places like tertiary care centre where chest radiography is freely available.

#### Evaluation of pleural fluid to serum cholinesterase ratio for differentiating exudates and transudates

*R. Logamurthy, Atharunnisa Begum and D. Ranganathan.*

**Aim:** To evaluate the utility of pleural fluid cholinesterase to its ratio with serum for differentiating Exudates and Transudates to compare its efficacy with Abbreviated Lights' criteria

**Material and Methodology:** About 80 cases with Pleural Effusion of diverse etiology were studied. These included Tuberculosis, Malignancy, Parapneumonic effusion and Effusions due to CCF and CRF .

The following criteria for distinguishing pleural fluid as Transudative or Exudative was measured:

- Pleural fluid cholinesterase level
- Serum cholinesterase level
- Pleural vs Serum cholinesterase Ratio
- Pleural vs Serum protein Ratio

**Conclusion:** The pleural fluid cholinesterase and its ratio with serum cholinesterase are one of the most accurate criteria in characterizing pleural effusions as exudates or transudates. The same can be used as the first step in diagnosis of pleural effusion. It is also cost-effective in resource poor settings.

**Pyrazinamide susceptibility testing of *M. tuberculosis* by BacT/ALERT 3D system, L-J Proportion Method and Pyrazinamidase assay**

*Pushpendra Singh, Abhay Kumar Mishra, Clement Wesley, Kalpana, Sunil Malonia, G.P.S. Jadaun, Jaya Faujdar, P. Upadhyay, P. Gupta, R. Das, O.S. Chauhan, Y.D. Sharma, U.D. Gupta, K Venkatesa and V.M. Katoch*

**Background:** Pyrazinamide (PZA) has been used in the therapy of tuberculosis for long time. A nicotinamide analogue pro-drug with sterilizing activity against semi-dormant tubercle bacilli, PZA requires bacterial Pyrazinamidase (PZase) enzyme activity for being converted into bactericidal moiety pyrazinoic acid (POA). MIC of PZA is pH dependant which makes PZA susceptibility testing difficult. Over the years, several liquid medium based rapid systems including radiometric BACTEC 460, fluorimetric MGIT 960 and colorimetric BacT/Alert system have been tested and found to be promising for PZA susceptibility testing. There has been no comparative evaluation of PZA susceptibility testing by BacT/ALERT 3D system, L-J Proportion Method and Pyrazinamidase assay.

**Objectives of the study:** Present study has been carried out to compare the results of PZA susceptibility testing by BacT/Alert system, L-J Proportion Method and Pyrazinamidase assay.

**Methodology of investigation:** A total of 107 isolates of *M. tuberculosis* were tested by L-J Proportion (Gold Standard), BacT/Alert and PZase assay as per the standard method described for these tests.

**Main findings:** A good concordance (90.65%) was observed among the results of these methods. Sensitivity of BacT/Alert system in present study (34/36=94.5%) was significantly better (P value

lesser than 0.05) than that of the PZase assay (29/36=80.56%) whereas no significant difference in their specificities was observed (P value more than 0.05). BacT/Alert system is a rapid and accurate method for PZA susceptibility testing with high sensitivity and specificity.

**MDR –TB : Treatment Outcome**

*S. Raiasekaran, P.R. Khaiser Ahamed, A. Mahilmaran, O.R. Krishnarajasekhar, S. Kumar, Dravidaselvanayagi and Mala*

**Background:** Government Hospital of Thoracic Medicine (GHTM), Tambaram, is the largest centre in India managing MDR- Tuberculosis. On any given day, there would be at least 140 in-patients receiving retreatment for MDR- TB.

**Objective:** To share the experience of GHTM in managing MDR-TB and to present the details of treatment outcome.

**Methodology:** Patients, who were confirmed to have MDR-TB admitted during 2002 to 2005, were considered for the analysis. The evaluation would cover pattern of drug resistance, drug regimens and treatment outcome.

**Results and Conclusions:** 400 patients were taken up for the analysis. The results were being compiled (at the time of abstract) and would be projected in greater detail.

**Prediction vs optimal diagnostic tool for MDR TB in developing countries**

*C. Venkatesh, R. Atharunnisa Begum and B. Rajagopalan*

**Objective:** To assess the value of prediction of drug resistance among CAT II failure cases

**Methodology:** All the Cat II failure cases attending the Institute of Thoracic Medicine, Chennai, were interrogated for detailed previous anti-tuberculous treatment history and subjected to thorough clinical-examination. Based upon the prior treatment history,

they were started empirically on an appropriate reserve regimen (Kan, PTH, Cipro, PAS & Pyz) after obtaining the sputum for AFB culture and drug sensitivity. When the drug sensitivity results were available, their regimens were reviewed for change of any drugs.

**Findings:** It is fascinating to see that more than 70% of the cases did not require any change in the prescribed regimen. Even in the group where they required any change, most of them were altered with only one drug and here found to be 80% of them were resistant to Ethionamide/Prothionamide. Less than 5% of the cases required more than two drugs change in their regimen.

**Conclusion:**

- In a specialised set up, it is quite possible to prescribe an appropriate reserve regimen with carefully taken previous treatment history.
- The formulated regimen should have at least FOUR new drugs, including one Aminoglycoside.
- The prescribed regimen should always be reviewed with sensitivity pattern wherever it is possible at the earliest

**Drug resistance profile among post-Cat II sputum positive patients - critical analysis**

*Mohamed Shafiq, R. Atharunnisa Begum and R. Sridhar.*

**Objective:** Evaluating drug resistance profile among patients reporting at Institute of Thoracic Medicine, Chennai, after taking Cat II under RNTCP and either failed, relapsed or defaulted from Cat II.

**Methodology:** Those patients who had treatment under RNTCP with Cat II and subsequently either failed or defaulted from treatment or relapsed after cure from Cat II from different districts of Tamilnadu and referred for further evaluation at Institute of Thoracic Medicine were included in the study.

All of them were subjected to sputum for

AFB culture and those patients who had culture positive also subjected to sensitivity studies. The sensitivity studies of these patients were evaluated with their previous ATT prior to Cat II, i.e. treatment outcome of Cat I.

**Findings:** 106 patients were evaluated who reported to Institute of Thoracic Medicine during the years 2004 & 2005 from different parts of Tamilnadu. The distribution of the cases are as follows:

Category II Status	Number	MDR	% of MDR
Failure	90	78	86.66
Relapse after Cat II	1	1	100
Treatment after default from Cat II	15	10	66.66
Total	106	89	83.96

**Conclusion:** The possibility of having MDR TB is found to be very high to the tune of 86.66% when a patient fails with Cat II under RNTCP. Hence the need for pre-treatment culture and sensitivity for patients who are entering into Cat II is stressed upon.

**A comparative study of use of cisplatin and talc as sclerosing agent in pleurodesis of malignant pleural effusions**

*Naveed Nazir Shah, Arshad Altaf Bachh, Rakesh Bhargava, Zuber Ahmed, D.K. Pandey and Mohd. Shameem*

**Objective:** To evaluate the efficacy and compare the outcome of pleurodesis using bleomycin and sterile talc as sclerosing agents in malignant pleural effusions.

**Material and Methods:** The study was carried out on patients attending the OPD/IPD of Department of TB & Chest Diseases. JNMCH, AMU, Aligarh. A total of 40 patients diagnosed as having malignant pleural effusion were selected. Out of these, 22 patients found eligible for pleurodesis were included

in our study while the rest 18 were excluded for reasons such as rapid progression of disease, non-expansion of lung and patients not willing to undergo the procedure. The selected patients were randomly divided into 2 equal groups. These two groups received either bleomycin (60 Units) or sterile talc (5-gms) intrapleurally through the intercostal tube as per the guidelines on management of malignant pleural effusions. Patients were evaluated for response after 4 weeks.

**Results:** Out of the 11 patients in the bleomycin group, pleurodesis was successful in 8 (complete response in 6 & partial response in 2), while in the talc group pleurodesis was successful in 9 (complete response in 6 & partial response in 3). There was no significant difference in the response rate in the bleomycin and talc group. No difference in adverse effect profile attributed to the drugs was noticed in the two groups.

**Conclusion:** Both bleomycin and talc are equally effective sclerosing agents in malignant pleural effusions. Since talc is cheap, it is a more cost effective agent.

#### **Clinical profile of female lung cancer from a tertiary care centre**

*P. Rekha, K.P. Venugopal and P. Sukumaran.*

**Introduction:** The incidence of lung cancer among females is increasing and it ranks fifth place among female cancers. Only few Indian studies are available on profile of female lung cancers.

**Study Objective:** To study the clinical profile of female lung cancers diagnosed from a tertiary care centre.

#### **Materials and Methods**

**Design :-** Prospective clinical study

**Study period :-** July 2004 -June 2005.

**Study centre:** Department of TB and Chest Diseases, Medical College, Kottayam

**Inclusion criterion:** Female inpatients of Department of Chest with a histological proof of lung malignancy.

Data collected according to the proforma with special emphasis on age, clinical presentation, radiological picture, investigations, diagnostic investigations, histopathological diagnosis and treatment options.

**Results:** Of the total lung cancers diagnosed (201), there were 36 females. Mean age was 55.2 years. 2 of the females were smokers and 70.56 % had history of passive smoking.

Thirty-two females were from rural population. The major clinical presentations were breathlessness (69.44%), cough (57.78%) and chest pain (55.56%). Mass (50%), Effusion (47.2%) and diffuse pulmonary opacities (30.56%) were the common radiological findings.

Transthoracic FNAC from the mass was the modality of investigation, which had maximum yield in arriving at a histologic diagnosis. Lymphnode FNAC/ excision biopsy were useful in 22.2%.

Adenocarcinoma was the most common histologic type of primary lung cancer (63.9%) followed by squamous cell carcinoma (8.3%), lymphoma (8.3%) and small cell carcinoma (2.8%). Metastasis (16.67%) were from breast, cervix and thyroid.

88.9% of the cases presented in stage III and IV. Only 3 cases were resectable. Others opted for chemotherapy (63.89%) or palliation (27.78%).

**Conclusion:** Female lung cancers constituted nearly 18% of total lung malignancies. Exposure to environmental tobacco smoke may be an attributable aetiological factor, which needs further evaluation.

Transthoracic FNAC from the mass lesion was the most useful investigatory modality in arriving at a histological diagnosis. Adenocarcinoma was the most common histological type of primary lung cancer.

### **Changing profile of lung cancers presentation in Govt. General Hospital, Chennai**

*R. Prabhakaran, V. Sundar, B. Rajagopalan, D. Ranganathan, and R. Athurunnisa Begum.*

**Aim:** To study the changing profile of lung cancers in year 1995 and year 2005.

**Method:** In the combined retrospective and prospective study, cases of lung cancers were scanned for distinctive (clinic pathological features, histopathological types and biological behaviour of the tumour.

**Results:** Total 83 diagnosed cases of lung cancer in 1995 were analysed in details. Male female ratio was 5.91 : 1, age range was from 35 to 87 years and maximum number of patients were between 46-64 years. Most common histopathological type in male was squamous cell carcinoma; most common histopathological type in females was adeno-carcinoma. Most common respiratory symptoms were cough 83.13%, hemoptysis 37.34% and chest pain 73.49%. Out of 83 patients, 61 patients were smokers, 22 were non-smokers. Most common cell type in smokers was squamous cell carcinoma followed by adeno-carcinoma. Among non-smokers most common cell type was adeno carcinoma.

All small cell carcinoma patients were smokers. 61.44% were having clubbing. Commonest presentation in chest radiograph was mass lesion (75.90%). Sputum cytology positive 7.22%, post FOB sputum cytology positive 15.66%, CT guided biopsy positive 85.36%, FOB guided biopsy positive 74.99%, USG guided biopsy positive 100% were noted.

This pattern has a few important differences when compared with recent 1 year study conducted in the same hospital in 2004 - 2005.

**Conclusion:** There is an increasing occurrence of lung cancer with a few definite changing patterns. Improved diagnostic method may be responsible. Smoking is the commonest etiological factor. Although squamous cell carcinoma is commonest

type but adeno carcinoma is also not uncommon.

### **Statistical analysis of risk factors with PFT abnormalities among traffic police personnel using a new risk scoring system**

*A. Chitrakumar, K. Jagannath and R. Altharunnisa Begum*

**Objective:** Identifying pulmonary function abnormalities among traffic police personnel serving in the city of Chennai and correlating the same with their respiratory symptoms and other risk factors as evaluated with a new scoring system introduced by us.

**Methodology:** All the eligible traffic police personnel were subjected to a respiratory questionnaire prepared specifically for the study and subsequently measurement of BP, Oxygen saturation and PFT by spirometer were done. All of them had a MMR. In all among 825 traffic police personnel screened, 768 were found eligible for inclusion in the study.

**Findings:** Pulmonary function abnormalities correlated well with persons with respiratory symptoms, age of the individual, smoking habit and duration of service in polluted environment.

The multiple logistic regression analysis revealed that respiratory symptoms were found to be significant independent variables contributing very significantly for abnormal PFT variables, i.e. FEV1 (or 1.79; p0.02), PEFR (or 1.58; p0.04), FEF 25-75 (or 2.40; p0.0001)

The new computer based scoring system on risk factors clearly predicts that increase in risk score is positively associated with increased proportion of PFT abnormalities in high risk groups.

**Conclusion:** The newly introduced risk scoring system will be quite useful in identifying or predicting pulmonary function abnormalities among respiratory symptomatics with other confounding variables. Among persons exposed to environmental pollution, evaluation of small airway function may help us to identify their disability at the earliest.

### **Immune Reconstitution Tuberculosis in HIV patients after Anti-retroviral Therapy**

*S. Rajasekaran, Satish Narayan, Vijila and N. Ravichandran.*

**Background:** Free Anti-retroviral therapy is being given to eligible people living with HIV in India since April 2004. Govt. Hospital of Thoracic Medicine, Tambaram Sanatorium, Chennai is one of the largest centres managing HIV/AIDS patients with Anti-retroviral therapy in India.

**Objectives:** This study finds out the Incidence of Tuberculosis as the manifestation of 'Immune Reconstitution Syndrome' after the initiation of Antiretroviral therapy in patients with HIV/AIDS.

**Methodology:** All the patients, placed under ART, are being followed up for the occurrence of Tuberculosis from April 2004 to November 2005 at GHTM, Tambaram Sanatorium, Chennai.

**Results:** 2,100 HIV patients were initiated Antiretroviral Therapy till November 2005 and of whom 1,461 (69.6%) were already treated for Tuberculosis. 302 (14.4%) had Immune reconstituted diseases and 80 (3.8%) had Tuberculosis, as the component of Immune Reconstitution Syndrome (IRS).

**Conclusion:** Occurrence of Tuberculosis as Immune Reconstitution manifestation is significantly high after antiretroviral therapy. This results in starting or restarting anti-tuberculosis treatment with the changed or modified antiretroviral therapy in a large number of patients.

### **Manifestation of Tuberculosis in HIV patients - A large Indian Study**

*S. Rajasekaran, S. Annadurai, Rabeetha, Mahesh, A. Mahilmaran, S. Kumar and K. Raja.*

**Background:** Govt. Hospital of Thoracic Medicine (GHTM), Tambaram Sanatorium, Chennai, is the largest HIV care centre in South East Asia. More than 28,000 HIV patients visited it in a calendar year for care and support.

**Objectives:** To identify the Clinical Manifestations of Tuberculosis among HIV patients attending the hospital for the first time and to assess the modes of presentation of Tuberculosis.

**Methodology:** Database of TB-HIV Patients Information System, especially evolved for GHTM, was utilized. The particulars confined to HIV- TB Co-infection among patients visited the hospital for the first time from January to November, 2005 were considered for the analysis.

**Results:** 14,487 HIV confirmed patients were screened for the possible presence of Tuberculosis. 4,176 (28.9%) had tuberculosis. Among those who had tuberculosis 2,703 (64.7%) had pulmonary TB and the remaining 1,473 (35.3%) had either disseminated or extra pulmonary TB. Sputum smear positivity for AFB was evident in 615 patients (15%).

**Conclusion:** Just over one fourth of the HIV patients were found to have manifestation of Tuberculosis at the time of detection of HIV. Sputum smear negative pulmonary tuberculosis and non-pulmonary tuberculosis were found to dominate the clinical presentation in HIV patients.

### **Linking of TB & HIV Programmes: Outcome of referral system: A Tamil Nadu experience.**

*S. Rajasekaran, K. Murugesan, A. Mahilmaran, O.R. Krishnarajasekhar, S. Kumar, S. Annadurai and P.R. Khaiser Ahamed.*

**Background:** National TB Control Programme is a well-integrated programme producing the desired results in the field conditions. National AIDS Control Programme is a vertical one till now, planning for 'mainstreaming' in NACP Phase III. Linking both the programmes needs enormous understanding, efforts and innovations.

### **Objectives:**

1. To identify the outcome of referred HIV patients with Tuberculosis to various centres and the percentage of them started on TB treatment, and
2. To find out the needs and mechanism to maximize the outcome of TB referrals to DOTS centres.

**Methodology:** HIV patients with Tuberculosis, who were referred to various DOTS centres in Tamilnadu from Govt. Hospital of Thoracic Medicine, Tambaram Sanatorium, Chennai, from January to October 2005, were taken up for analysis. Feedback from the DOTS centres and from the patients, on their follow up visit to GHTM, formed the basis of outcome of the referral system.

**Results:** One thousand six hundred and eighty-two HIV patients with Tuberculosis were referred to DOTS Centres in Tamilnadu from GHTM, Tambaram. Feedback of starting treatment for TB was received from DOTS centres and patients themselves to the tune of 1,049 (62%). Individual stigma and fear of discrimination among HIV patients were found to be the major factors for non-reporting of patients to the DOTS centres. Ignorance and Misconception of HIV and indifference towards HIV patients among Health Care workers in peripheral centres were the other important reasons.

**Conclusions:** Creating a non-stigmatised and non-discriminatory atmosphere in the field condition is necessary for accessing DOTS centres by HIV patients for TB treatment. Many suggestions were detailed in the presentation.

#### **HIV/TB The Brewing Double Trouble - A Seroprevalence Study**

*Rajinder Kumar Goyal, P.K. Garg, V.B. Singla, A.P. Kansal, Vishal Chopra and Charanpreet Grover.*

The objective was to determine the prevalence on HIV Infection to patients or pulmonary tuberculosis. A total of 250 (170 males & 80 females) consecutive sputum positive Pulmonary Tuberculosis cases between 15 and 45 years, admitted to the Department of Chest & TB, Government Medical College, Patiala, were screened by ELISA Test for HIV. Out of them 13(5.2%) were found to be HIV positive which were later confirmed by Rapid Tests. The 25-35 year age group had the highest seroprevalence. Fever and cough with expectoration were the most common presenting complaints. Unilateral X-ray Chest abnormality was

present in 185 (73.6%) and bilateral X-Ray Chest abnormality was present in 65 (26.4%) of the patients.

#### **Pulmonary Involvement In Marfan's Syndrome - A Rare occurrence**

*A.P. Kansal, Udham Chand, P.K. Garg, Vishal Chopra, Balvinder Kaur and Sudesh Kumari*

A 17 year old female patient presented with chief complaints of breathlessness, dry cough and chest pain for 3 months. Breathlessness was present on exertion, cough was dry in nature and was not related to posture. On clinical examination, she was anaemic. Arachnodactyly and alopecia were present. She was 161 cm. tall and her arm span was 165 cm. Upper body length was 80 and lower body length was 81 cm. Laboratory investigations revealed that Hb was 8.5 gm% while all other parameters were within normal limits. Sputum for AFB & malignant cells was negative. LE Cell and ANCA were negative. CXR showed lesion in all zones bilaterally. Echocardiography showed MVP and AR with a normal LV function. CECT Chest showed extensive cystic lesions with honeycombing changes in all zones, mainly in upper lobes. She was diagnosed as a case of ILD with Marfan's Syndrome. She was started with Tab. Prednisolone 0.7mg/Kg and she responded well. Marfan's Syndrome is an autosomal dominant disorder due to mutation on chromosome 15 and is a rare entity with an incidence of 1 in 10000, hence the reason for reporting the case.

#### **Correlation of HRCT and functional and broncho alveolar cytologic findings in interstitial lung diseases associated with collagen vascular disorders.**

*A. Mahesh Kumar, Sundar, D. Rangnathan and Atharuninnsa Begum.*

**Aim:** To quantify the severity and extent of the interstitial lung disease as depicted in HRCT and to study the relationship between these patterns and the functional parameters and broncho alveolar lavage findings in patients with collagen vascular diseases.

**Patients:** Sixty non-smoking patients (22 with systemic sclerosis, 20 with rheumatoid arthritis, 6 with Sjogrens' syndrome, 5 with SLE, 4 with dermatopolymyositis and 3 with overlap syndrome) were examined.

**Results:** Fifty-five of 60 patients (91.66%) had abnormal HRCT findings( septal/subpleural thickening, ground glass pattern. Chest X-ray showed parenchymal abnormalities in (58.18%) who had evidence of fibrosis on HRCT. Abnormal differential cell counts (alveolitis) at BAL were found in (76.66%). Following types of alveoli tis were found: pure lymphocytic, pure neutrophilic and mixed cellularity or with normal patterns. The extent of reticular and ground glass pattern on HRCT correlated with neutrophil rate and the lymphocyte/eosinophil/total count respectively. Lung volumes were significantly different between these two radiological patterns.

**Conclusion:** HRCT is a sensitive tool in detecting ILD and ranks superior to chest X-ray in collagen vascular disease patients. The relationship between the different HRCT patterns and BAL cell profiles can identify the patients at higher risk of developing irreversible fibrosis.

### **Esophageal Diverticuli - A Rare Cause of Chronic Cough**

*A.P. Kansal, Charanpreet Singh Grover, Sallrabh Kansal and Rajesh Rana.*

Esophageal diverticula are outpouching of the wall of the esophagus. These diverticuli are usually asymptomatic but may lead to dysphagia, cough or stricture formation. A case of 60-year female patient presented with complaints of chronic cough and dysphagia, since 5 years. Patient had already been operated for Achalasia Cardia 33 years back. The dysphagia was non-progressive and more to solids than to liquids. All routine investigations were normal except microcytic hypochromic anaemia. Patient had been on symptomatic treatment since then but the symptoms persisted and after that the patient reported to our hospital. Chest X-ray showed a well defined homogenous opacity continuous with the hilum and

possibility of malignancy was considered. NCCT Chest showed epiphrenic diverticulum arising from lower end of thoracic esophagus with atelectasis in surrounding posterior basal segment of left lower lobe. Upper Gastrointestinal Endoscopy showed a mass obliterating the lumen of esophagus. Barium swallow study findings revealed dilated esophagus in its entire length displaying tertiary contractions due to partial obstruction at lower end with some herniation of part of stomach superiorly. Biopsy from the growth confirmed gastric hyperplastic glands with no evidence of malignancy. A diagnosis of esophageal diverticuli was made and the patient was treated symptomatically for its chronic cough which was due to pressure effects on the respiratory tract. The case was then advised and referred for surgery.

### **Endobronchial Tuberculosis – our experience**

*K.P. Venugopal, P. Rekha, and P. Sukumaran.*

**Introduction:** Endobronchial Tuberculosis is defined as tuberculous infection of tracheobronchial tree with microbial or histopathological evidence. It comprises 10-40% of pulmonary tuberculosis (as such rare). We are presenting our experience with Endobronchial Tuberculosis.

**Setting and Methods:** The study was conducted in the Department of TB & Chest Diseases, Medical College, Kottayam, a tertiary care hospital. This was done as a retrospective study of endobronchial tuberculosis cases detected by fibre-optic bronchoscopy from 1/8/05 to 1/1/06.

**Results:** Out of 600 bronchoscopies done for various indications, 5 turned out to be biopsy positive for endobronchial tuberculosis.

Mean age was 26 (14 - 48 years) with 3 males and 3 females. All presented with fever, cough and weight loss, 4 had haemoptysis.

Initial clinical diagnosis was non-resolving pneumonia in 2, collapse in 2 and asthma in 1. All were initially sputum AFB negative. Bronchoscopy showed intraluminal lesions in all and one showed significant stricture also. Histopathology came as

granuloma suggestive of tuberculosis in all. Two patients had post-bronchoscopic sputum AFB +ve.

All were started on category I, ATT and showing good clinical response. One showed significant bronchial stricture and others were followed up. Further details with X-rays video clippings and HPR slides were presented.

#### **Seasonality in Tuberculosis: Three years' observation under DOTS**

*V.K. Dhingra, S. Rajpal, Nishi Agarwal and Anshu Mittal*

**Introduction:** Many diseases are known to have seasonal variations e.g. bronchial asthma, influenza, viral fevers, measles, chicken pox, gastro-enteritis, hepatitis, etc. Cases of tuberculosis although seen throughout the year seem to have a seasonal variation as well. An attempt was made to find out seasonality in reporting pattern of chest symptomatics and registration of tuberculosis cases, if any, in the domiciliary area of New Delhi Tuberculosis Centre.

#### **Aims and Objectives:**

1. To study the seasonal trend in the reporting of chest symptomatics and sputum positivity among those presenting at DOT Centres of New Delhi Tuberculosis Centre.
2. To study the relation of sex, type of tuberculosis with seasonality in the registration pattern.

**Material and Methods:** Patients with chest symptoms presenting to New Delhi Tuberculosis Centre from January 2002 to December 2004 were examined for Acid Fast Bacilli by direct smear examination using Z.N. Staining technique. The record was reviewed and compared for summer (April to September) and winter months (October to March) of each year using the Chi square test. The pattern of reporting and the yield of positive disease diagnosed was assessed with a view to study seasonal variation.

**Results:** Out of total 6,850 chest symptomatics examined, 1,089 (15.9%) were positive for AFB. During summer, the attendance of chest symptomatics and the number of patients diagnosed and treated was significantly higher than during winter. While sputum positive patients were more likely to be males ( $P < 0.05$ ), extra pulmonary disease was significantly higher in females ( $P < 0.05$ ).

**Conclusion:** Pulmonary tuberculosis appears to have a seasonal variation with more cases presenting for diagnosis and treatment during summer.

#### **HIV -TB Co-Ordination In Maharashtra State**

*Pooja Singh and A.B. Patil*

**Background:** TB and HIV are amongst the major public health problems in India. Around 40% Indian population is TB-infected and an estimated 0.9% of adult population is HIV-infected. HIV infection is a strong risk factor for progression from TB infection to disease. Maharashtra, with a population of more than one hundred million, has an estimated 1.4 million seropositives and an estimated 180,000 new TB cases each year.

#### **Objectives:**

- 1) To find out the proportion of TB suspects diagnosed as TB cases and put on treatment, out of those referred for investigation among clients attending the VCTC.
- 2) To describe the methods of VCTC-RNTCP Co-ordination.

**Methods:** Under the TB-HIV Co-ordination Programme initiated in 2001 in Maharashtra, the VCTC-DMC/DOT referral linkage was established with the objective of identifying TB suspects amongst VCTC clients and referring them to Designated Microscopy Centers (DMCs) for the early detection of TB and treatment initiation. There is one VCTC in each of the districts. The VCTC counsellor and the TB treatment supervisor jointly prepare the line-list

of referrals made from VCTC to DMC/DOT Centre.

**Results:** Between 1<sup>st</sup> January, 2005 to 30<sup>th</sup> June 2005, 2,209 VCTC clients were identified as TB suspects, out of which 560 (25%) were diagnosed as TB cases. 396 (71%) patients were put on DOTS. VCTCs contributed 0.75% of the total TB cases registered during the study period in Maharashtra. Out of 1,108 HIV-positive patients, suspected to have TB, which were referred from VCTC to DMC, 143 patients were diagnosed as smear positive TB, 98 as smear negative TB and 35 as extra-pulmonary TB. Amongst 1,101 HIV-negative patients referred as TB suspects, 178 were diagnosed as smear positive TB, 88 as smear negative TB and 28 as extra-pulmonary TB.

**Conclusions:** The referral linkage between VCTC and DMC has enhanced TB case detection amongst clients attending VCTC, and shows a sustainable framework to improve TB control.

**Tuberculosis presenting as Osteolytic soft tissue swellings of skull in HIV positive patient: A case report.**

*A.K. Tripathy, N. Gupta, M. Khanna, R. Ahmad and P. Tripathi*

Tuberculosis of bone may evade diagnosis for a long time, as it usually remains silent till either involvement of a neighboring joint or development of a soft tissue swelling due to cold abscess formation. The osteolytic lesions of tuberculosis may closely mimic those due to multiple myeloma or secondary malignant deposits. Tuberculosis of flat bones of the skull vault is relatively a rare disease. The skull lesions are usually secondary but primary disease have also been reported though uncommonly. Osteolytic lesions of the skull are an unusual complication in patients with AIDS. Other important causes are multiple myeloma, secondary metastasis and bacterial osteomyelitis. A case of tuberculosis presenting with osteolytic soft tissue swelling of skull in middle aged HIV positive male is reported. This was a clinical case discussion of a 40 year old HIV positive male patient presenting with fever, cough and expectoration and osteolytic, cystic, multiple soft tissue swellings of skull (aspirate showing AFB+++).

**Time lapse between onset of illness and visit to DOT-cum-Microscopy Centre**

*Meera Dhuria, Nandini Sharma, K.K. Chopra, R. Saha and G.K. Ingle.*

**Background:** Delay in the diagnosis of tuberculosis may worsen the disease, increase the risk of death and enhance tuberculosis transmission in the community. This study aims to determine the time lapse between the onset of symptoms and patient's visit to DOT cum microscopy centre.

**Methods:** A cross sectional survey that included two DOT centres was conducted in New Delhi from March to May 2005. Patients were interviewed using structured questionnaire.

**Results:** Hundred TB patients were studied. The median time lapse in reporting was two months amongst the study subjects. Fourth per cent of the patients reported to a DOT-cum-microscopy centre within two months of onset of symptoms. One fifty (20%) of the patients reported to a DOT cum microscopy centre eight months after the onset of symptoms. Patients of Cat I reported significantly earlier to a DOT-cum-microscopy centre as compared to Cat II and Cat III. Private practitioners emerged as a first source of treatment among majority of patients. Significantly more literate patients reported earlier than illiterates. However, there was no significant difference in relation to age, sex and socio-economic status.

**Conclusions:** There is a need of generating awareness among people for early care seeking (self perceived) rather than visiting other sources. The private practitioners and doctors of other systems of medicine should be sensitized to the importance of early reporting.

**A new measurable indicator for Tuberculosis (TB) case detection in Revised National TB Control Programme (RNTCP)**

*P.G. Gopi*

**Introduction:** RNTCP recommends a case detection

rate (CDR) of 70% of new smear-positive cases. COR is the number of reported cases per 100,000 persons annually divided by incidence per 100,000 per year. The incidence is uncertain, not measured but estimated. An alternative indicator is patient diagnostic rate (PDR), which is measured as number of reported cases per 100,000 persons annually divided by prevalence per 100,000 per year.

**Objective:** To estimate the PDR and compare it with CDR.

**Methodology:** TB Research Centre has generated data on prevalence and incidence among the adult population aged 15 years and above from community surveys in a rural area of 580,000 population in Tiruvallur district, Tamil Nadu after implementation of RNTCP. TB Patients attending the health facilities

were registered under RNTCP. The prevalence and incidence of TB and the number of cases reported per 100,000 per year (notification rate) were used to estimate PDR and CDR. The estimation of PDR is restricted to the new cases.

**Results:** The prevalence and incidence of new smear-positive cases were 153 and 127 respectively per 100,000 as estimated from the survey conducted during 2001-2003. During 2003, 446 new smear-positive cases were detected and treated. Assuming 70% of the general population aged  $\geq 15$  years, the notification rate was 11 0 11 00,000. The PDR was 72% against the CDR of 87% in 2003.

**Conclusion:** Monitoring the TB control programme measured by PDR through prevalence survey is reliable compared to CDR estimated from incidence.

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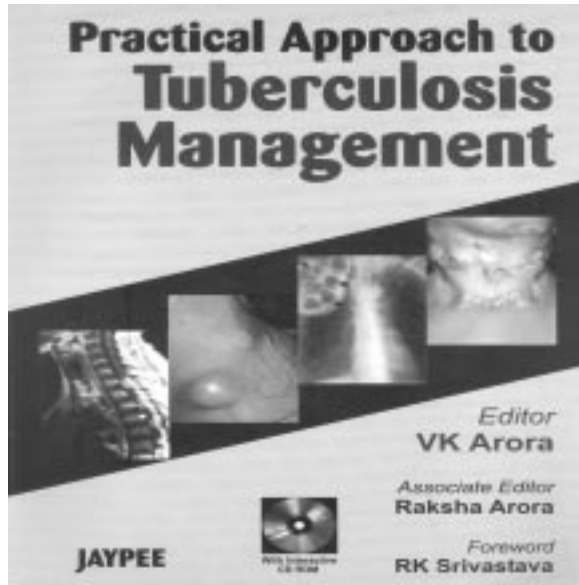
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**BOOK REVIEW**

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**Practical Approach to Tuberculosis Management: (Editor) V.K. Arora (Associate Editor) Raksha Arora, published by Jaypee Brothers Medical Publishers (P) Ltd., EMCA House, 23/23B, Ansari Road, Darya Ganj, New Delhi-110 002; 710 pages, 55 Chapters with black and white X-ray illustrations, 13 coloured plates, 6 appendices, 1 inter-active CD ROM, ISBN 81-8061-767-X; Price Rs. 895/-.**



Tuberculosis is a multi-systemic disease and has varied presentations. The disease, producing different clinical manifestations, can involve every organ of the body and a patient may present with complications to any specialist, sometimes with diagnostic dilemma and at other times with management problems like MDR-TB. To the national health managers, it poses a problem of control of the disease in the community. Keeping this in mind, eminent scientists in the field of epidemiology, microbiology, clinical management and tuberculosis control from various prestigious research institutes from all over the country have contributed their experiences and critical issues related to tuberculosis in this book.

The chapters in this book are arranged in a scientific sequence in a flow to aid easy understanding. The topics included provide relevant

theoretical basis, practical management strategies as well as new advancements in the particular subject. This multi-authored book has been conceived with compilation of case oriented practical approach chapters, concisely blended with updated information to cater to the needs of the present day demand in medical curricula. The book is also equipped with the latest advances in diagnosis and management of tuberculosis in the form of appendices at the end of book. The appendices include guidelines for various activities under Tuberculosis Control Programme of Government of India.

The unique feature of this book is the presentation of different aspects of the disease as experienced by the eminent practitioners in the field of respiratory medicine and tuberculosis and their hand-on experience in dealing with the conditions to achieve the successful outcome. The chapters have been written in the background of their rich academic knowledge gained from day to day dealing with the patients.

The book is a compilation of the experiences and learning of a galaxy of faculties who have already made their place in the hall of fame in pulmonary medicine. This textbook is different from the traditional contemporaries in a way, that it speaks rather than being read, as each of the topics has 'A Case Based Approach'. This provides the reader with a patient-directed framework from which sound clinical reasoning is explored. The individual cases and their respective clinical problems have been selected with the intent of improving clinical reasoning and strengthening the reader's knowledge base. It is the cohort that strives to link patient complaints to disease and therapy.

**M.M. Singh & K.K. Chopra**

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ABSTRACTS

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**Cost determinants of tuberculosis management in a low-prevalence country**

M. Bocchino et al. *Int J Tuberc Lung Dis* 2006; **10(2)**: 146-152.

This is a retrospective evaluation of tuberculosis (TB) care associated costs in an integrated in and out-patient management programme. Review of the medical records of 92 human immuno-deficiency virus negative TB cases admitted between September 2000 and May 2003 was done. Length of in-hospital stay ( $45 \pm 35$  days) was the major cost determinant, as hospitalisation accounted for almost 80% of the total costs of the case, with fixed bed-per-day charges amounting to 76% of hospital costs. Factors associated with higher costs were chest X-ray score, fever, sputum bacterial load and multi-drug resistance ( $P < 0.05$ ). Cure/treatment completion was achieved in 82% of patients entering the out-patient programme (63% of all cases). Homelessness, age and co-morbidities were associated with unfavourable outcomes. A closely followed hospital-centred protocol carried out in a high-resource setting may produce acceptable cure/completion treatment rates. As a too high fraction of resources invested in TB control goes toward hospital costs, out-patient treatment strategies should be implemented.

**An alternative method for sputum storage and transport for *Mycobacterium tuberculosis* drug resistance surveys**

R. Lumb et al. *Int J Tuberc Lung Dis* 2006; **10(2)**: 172-177.

The objective was to evaluate whether a single sputum specimen could be stored by refrigeration for an extended period of time, then transported to a reference laboratory and successfully cultured for *Mycobacterium tuberculosis*. Single sputum specimens were collected from newly diagnosed smear-positive pulmonary TB patients, refrigerated at the study site without addition of 1% cetylpyridinium chloride, batched and sent to the reference laboratory, where they were decontaminated and inoculated into BACTEC MGIT

960 liquid media. One hundred and seven patients were enrolled. The median specimen storage time was 12 days (range 1-38) and median transportation time was 4 days (2-12). The median time from specimen collection until processing was 18 days (4-42). Only 4 (3.7%) specimens failed to grow *Mycobacterium species* and *M. tuberculosis* was isolated from 101 (94.4%) specimens. Six specimens with breakthrough contamination successfully grew *M. tuberculosis* after a second decontamination procedure. Single sputum specimens collected at a remote setting, refrigerated for relatively long periods without preservatives and transported without refrigeration to a reference laboratory can yield a high positive culture rate. These findings offer potential logistic simplification and cost savings for drug resistance surveys in low-resource countries.

**Using tuberculosis suspects to identify patients eligible for anti-retroviral treatment**

L. Munthali et al. *Int J Tuberc Lung Dis* 2006; **10(2)**: 199-202.

The study was conducted in a district in rural sub-Saharan Africa with a recently introduced anti-retroviral (ARV) programme. The population has high human immuno-deficiency virus (HIV) prevalence and high tuberculosis (TB) incidence. The objective was to determine the prevalence of HIV and acquired immune-deficiency syndrome (AIDS) related symptoms in people presenting with chronic cough who are not diagnosed with TB. Patients with chronic cough were recruited from outpatient facilities. After standard diagnostic procedures and providing informed consent, they received counselling and testing for HIV; and were interviewed and examined with respect to staging criteria for HIV/AIDS. Suspects were followed up for 3 months after the end of the recruitment period to allow for delayed diagnosis of TB. Of 145 suspects, 79% had not been diagnosed with TB by the end of the follow-up period. Of these, 108 (95%) agreed to HIV testing and 61 (56%) were HIV-positive. More than half of these were eligible for ARV treatment (Stage III or IV

disease) under national programme criteria. Established chronic cough clinics are a useful setting for recruitment of patients to ARV clinics. Attendees should be offered HIV testing and simple clinical screening to identify those who should be referred for ARV treatment.

#### **Factors affecting patient adherence to DOTS**

T.S. Bam et al. *Int J Tuberc Lung Dis* 2006; **10(3)**: 270-276.

The study was conducted in an urban area of Kathmandu, which has a population of one million, with an annual risk of tuberculosis (TB) infection of 4%. It is estimated that up to 200 people default from treatment in Kathmandu annually, giving a defaulter rate of 10%. Objective was to identify the socio-demographic factors, availability and accessibility of DOTS services and behavioural factors affecting patient adherence to DOTS. Analysis of socio-demographic, psychosocial factors and availability and accessibility of DOTS services was done by using a structured questionnaire of a random sample of 234 new smear-positive TB patients enrolled on treatment. Sub-analysis of non-adherent (missed >7 consecutive treatment days) vs adherent patients. Reasons given by non-adherent patients included 61% who claimed insufficient knowledge about the need to take daily treatment, especially after they felt better. Directly observed treatment, younger age, knowledge of TB and availability of daily health education were associated with increased adherence. Daily health education and knowledge of TB and its treatment were independently associated with adherence on multivariate analysis (OR 6.27, 95% CI 2.88-13.64,  $P < 0.001$ ). Daily health education delivered at DOTS centres is strongly associated with improved adherence. Adherence throughout treatment needs emphasis.

#### **Tuberculosis drug resistance and treatment outcomes under DOTS settings .**

A. Ohkado et al. *Int J Tuberc Lung Dis* 2006; **10(3)**: 283-289.

To describe the problems of drug-resistant tuberculosis (TB) in an urban setting, with special

emphasis on their potential impact on the treatment services provided by the National TB Control Programme, a cross-sectional survey and cohort analysis of treatment outcomes was done. All patients with positive sputum smear examination results in Cebu and Mandaue cities during the survey period were included. The survey procedures of the World Health Organization and the International Union Against Tuberculosis and Lung Diseases were strictly applied. Treatment outcome data were also collected. 306 cases enrolled, 255 were new cases, 28 were previously treated and for 23 treatment history was unknown. Of the new cases, 72.2% were pan-susceptible to all four first-line anti-tuberculosis drugs. Resistance in new cases was 16.9% to Isoniazid (INH), 4.7% to Rifampicin (RMP), 3.1% to Ethambutol, 18.0% to Streptomycin, and 3.9% to at least both INH and -RMP (multi-drug-resistant [MDR]). Over 90% of the new cases, either pan-susceptible or mono-resistant, were successfully treated with the standard regimen, but four of nine MDR new cases could not be cured. The drug resistance level was high in this population, but treatment outcome using the standard treatment regimen was not seriously affected unless the patients were MDR.

#### **Representative drug susceptibility patterns for guiding design of retreatment regimens for MDR-TB**

M.L. Rich et al. *Int J Tuberc Lung Dis* 2006; **10(3)**: 290-296.

There is no gold standard on how national tuberculosis programs should design retreatment regimens. Often drug susceptibility testing (DST) is not available for all patients, and representative DST patterns in patient populations are used to guide therapy. To examine DST patterns in different patient populations based on previous treatment and to estimate the number of effective anti-tuberculosis agents in several retreatment regimens, we reviewed DST results from patients treated with individualized regimens in Peru between January 1998 and July 2004. We stratified patients into four groups based on previous treatment exposure from Group 1 who had failed only one regimen to Group 4 who had failed three regimens. We compared resistance frequencies across the four groups. In Groups 1

and 3, the number of likely effective agents under six possible retreatment regimen scenarios was estimated. Resistance to second-line drugs was significantly higher in groups with more previous courses of treatment. A few retreatment regimens could be identified that would allow at least 80% of patients to receive at least four likely effective drugs. Because it is associated with resistance frequencies, previous treatment exposure can serve to guide the design of non-individualized MDR- TB regimens.

**Comparison of Mantoux skin test with three generations of a whole blood IFN- $\gamma$  assay for tuberculosis infection.**

H. Mahomed et al. *Int J Tuberc Lung Dis* 2006; **10(3)**: 310-316.

Objective was to compare the performance of QuantiFERON assays with the tuberculin skin test (TST) for identifying latent tuberculosis infection (LTBI) in a high TB burden community. In a cross-sectional study in healthy adults, we applied the TST and took blood for the three generations of QuantiFERON assays. Of 358 participants whose results were analysed, 291 (81%) had a TST result of  $\geq 10$  mm induration, and 187 (52%)  $\geq 15$  mm. QuantiFERON-TB was positive in 215 (60%), QuantiFERON-TB Gold in 137 (38%), and QuantiFERON-TB Gold (In-Tube method) in 201 (56%). There was poor agreement between TST and QuantiFERON tests, and between the different generations of QuantiFERON tests ( $K = 0.12-0.50$ ). Of the subset with TST indurations  $\geq 15$  mm, 30-56% had negative QuantiFERON tests. However, positive QuantiFERON tests were associated with males, who have a higher incidence of TB in this area. We showed poor agreement between TST and the different QuantiFERON tests in diagnosing LTBI. The surprising discordance between the QuantiFERON TB Gold and QuantiFERON TB Gold (In Tube method) tests needs to be investigated further.

**Efficacy of intra-muscular BCG polysaccharide nucleotide on mild to moderate bronchial asthma accompanied with allergic rhinitis.**

L.I. Jing et al. *Chinese Medical Journal* 2005; **118(19)**: 1595-1603.

Atopy is a state of allergy to common

antigens and is founded on an immune disturbance of exuberant Th2 activity and IgE production. There is also epidemiological and experimental evidence that exposure to mycobacteria has the potential to suppress the development of asthma or atopy. Since Th1 and Th2 immune mechanisms are significantly antagonistic, it is hypothesized that mycobacterial exposure may moderate atopic disease by modification of immune responses. One hundred and twenty mild to moderate persistent asthmatics accompanied with allergic rhinitis were randomly divided into four groups with one injection every other day for 18 times for group A with 1 ml of normal saline, B with 0.5 mg of Bacillus Calmette-Guerin polysaccharide nucleotide (BCG- PSN) and C with 1 mg of BCG-PSN, 36 times for group D with 0.5 mg of BCG-PSN. Markers for the severity of asthma and rhinitis including the amount of inhaled corticosteroid, bronchodilator and oral H<sub>1</sub> blocker loratadine being used to obtain optimal symptomatic control, symptom scores of asthma and allergic rhinitis, peak expiratory flow (PEF), histamine provocative dose that produces at least a 20% change in forced expiratory volume with in 1 second ( $PD_{20}-FEV_1$ ), blood IgE levels as well as dermatophagoides pteronysinus (DP) and dermatophagoides farinae (DF) skin prick test were measured every visit for 6 months. There were no differences for symptom scores of asthma, daily use of bronchodilator, PEF,  $PD_{20}-FEV_1$  blood IgE as well as DF and DP skin prick test among the four groups. Score for allergic rhinitis decreased significantly in groups B, C and D on day 36 and 72 as compared with group A ( $P < 0.05$ ). Score for allergic rhinitis increased after day 72 in group B and C while it was significantly lower in group D ( $P < 0.05$ ). The patients in group D used less amount of inhaled beclomethosone than other groups ( $P < 0.05$ ) from day 72 after the treatment to day 180. Oral loratadine consumption in groups B, C and D was significantly less on day 36 and 72 as compared with their baseline and group A after the treatment ( $P < 0.05$ ). Group D maintained significantly lower dosage of oral loratadine until day 150 comparing with its baseline and group A. BCG-PSN has a symptomatic effect on allergic rhinitis. BCG-PSN may reduce the dosage of non- sedative H<sub>1</sub> blocker loratadine as well as the dosage of inhaled beclomethosone in

the treatment of mild to moderate asthma and allergy.

**Pulmonary infection control window in treatment of severe respiratory failure of chronic obstructive pulmonary disease.**

Collaborating Research Group for Non-invasive Mechanical Ventilation of Chinese Respiratory Society. *Chinese Medical Journal* 2005; **118(19)**: 1589-1594.

Early withdrawal from invasive mechanical ventilation (MV) followed by noninvasive MV is a new strategy for changing modes of treatment. This study was conducted to estimate the feasibility and the efficacy of early extubation and sequential non-invasive MV commenced at beginning of pulmonary infection control window in patients with exacerbated hypercapnic respiratory failure caused by chronic obstructive pulmonary diseases (COPD). A prospective, randomized controlled study was conducted in eleven teaching hospitals' respiratory or medical intensive care units in China. Ninety intubated COPD patients with severe hypercapnic respiratory failure triggered by pulmonary infection (pneumonia or purulent bronchitis) were involved in the study. When the pulmonary infection had been controlled by anti-biotics and comprehensive therapy, the "pulmonary infection or control window (PIC window)" has been reached. Each case was randomly assigned to study group (extubation VI and non-invasive MV via facial mask immediately) or control group (invasive MV was received continuously after PIC window by using conventional weaning technique). Study group ( $n = 47$ ) and control group ( $n = 43$ ) had similar clinical characteristics initially and at the time of PIC window. Compared with control group, study group had shorter duration of invasive MV [ $(6.4 \pm 4.4)$  days vs  $(11.3 \pm 6.2)$  days,  $P = 0.000$ ], lower rate of ventilator associated pneumonia (VAP) (3/47 vs 12/43,  $P = 0.014$ ), fewer days in ICU [ $(12 \pm 8)$  days vs  $(16 \pm 11)$  days,  $P = 0.047$ ] and lower hospital mortality (1/47 vs 7/43,  $P = 0.025$ ). In COPD patients requiring intubation and invasive MV for hypercapnic respiratory failure, which is exacerbated by

pulmonary infection, early extubation followed by non-invasive MV initiated at the start of PIC window may decrease significantly the duration of invasive MV, the risk of VAP and hospital mortality.

**Non-invasive versus invasive mechanical ventilation for respiratory failure in severe acute respiratory syndrome.**

Loretta Y.C. Yam et al. *Chinese Medical Journal* 2005; **118(17)**: 1413-1421.

Severe acute respiratory syndrome is frequently complicated by respiratory failure requiring ventilatory support. We aimed to compare the efficacy of non-invasive ventilation against invasive mechanical ventilation in treating respiratory failure in this disease. Retrospective analysis was conducted on all respiratory failure patients identified from the Hong Kong Hospital Authority Severe Acute Respiratory Syndrome Database. Intubation rate, mortality and secondary outcome of a hospital utilizing non-invasive ventilation under standard infection control conditions (NIV Hospital) were compared against 13 hospitals using solely invasive ventilation (IMV Hospitals). Multiple logistic regression analyses with adjustments for confounding variables were performed to test for association between outcomes and hospital groups. Both hospital groups had comparable demographics and clinical profiles, but NIV Hospital (42 patients) had higher lactate dehydrogenase ratio and worse radiographic score on admission and ribavirin-corticosteroid commencement. Compared to IMV Hospitals (451 patients), NIV Hospital had lower adjusted odds ratios for intubation (0.36, 95% CI 0.164 - 0.791,  $P = 0.011$ ) and death (0.235, 95% CI 0.077 - 0.716,  $P = 0.011$ ), and improved earlier after pulsed steroid rescue. There were no instances of transmission of severe acute respiratory syndrome among health care workers due to the use of non-invasive ventilation. Compared to invasive mechanical ventilation, non-invasive ventilation as initial ventilatory support for acute respiratory failure in the presence of severe acute respiratory syndrome appeared to be associated with reduced intubation need and mortality.

**K.K. Chopra**

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## GUIDELINES FOR CONTRIBUTORS

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### GENERAL

The *Indian Journal of Tuberculosis (IJT)* is published four times in a year; January, April, July and October. It publishes original articles on tuberculosis, respiratory diseases, case reports, review articles, and abstracts of articles published in other medical journals and book reviews. Every issue contains editorial, sections on contemporary subjects, radiology forum and a forum for readers to express their opinions on published articles or raise questions on subjects appearing in the journal.

### SUBMISSION OF ARTICLES

All correspondence relating to the *IJT* should be addressed to: *The Editor, Indian Journal of Tuberculosis*, Tuberculosis Association of India, 3 Red Cross Road, New Delhi - 110 001. Articles can also be sent by e-mail at [tbassnindia@vsnl.net](mailto:tbassnindia@vsnl.net) and [tbassnindia@yahoo.co.in](mailto:tbassnindia@yahoo.co.in).

Articles are published on the understanding that every author confirms his participation in the study concerned and approves its content, and an affirmation that the article is original and has not been published/submitted for publication elsewhere and will not be so submitted, if accepted for publication in the *IJT*. A letter to this effect signed by the author should accompany the article.

All received articles are published, if found suitable, after completion of basic formalities. Notification of acceptance or rejection will be sent within three months of receipt. The decision of the Editor is final who reserves the right to make editorial corrections.

### PREPARATION OF MANUSCRIPTS

Manuscripts should conform to the Uniform Requirements for Manuscripts submitted to the Biomedical Journals (for further details see *Ann Intern Med* 1997; 126: 36-47). Articles on clinical research

should conform to the standards defined in the Helsinki Declaration.

Three copies of the manuscripts, including diagrams and photographs, typed on one side of the paper with double spacing and wide margins should be submitted. In order to facilitate refereeing, it would be appreciated if compact diskettes are also enclosed. The preferred package is MS Word. The author should mention e-mail address, telephone number and fax number apart from complete postal address with PIN code.

All submitted manuscripts should have a definite format comprising the following sections: Title page, Summary, Introduction, Material and Methods, Results, Discussion, Acknowledgements and References.

#### Title page

This should contain: 1. A concise informative title; 2. The name of the principal author followed by names of other authors without giving qualification or position held except as numeral on top of last letter of name; 3. A running head usually not exceeding 5 words; 4. A word count of the text, excluding references, tables and figures; 5. In the case of original articles, a few key words for indexing purposes, using where possible, terms of medical subjects headings list from index medicus. The position held by each author in any institution should be indicated at the bottom of the title page along with the name and address of the author to whom correspondence regarding the manuscript has to be sent. E-mail addresses, if available, should also be given.

#### Summary

An informative summary of not more than 250 words should be provided that can be understood without reference to the text (see *Ann Intern Med* 1990; 113: 69-76). The summary should be as per Vancouver format as follows: Background, Aims,

Methods, Results and Conclusions. Unstructured summaries may be submitted for review articles, case reports and short communications (100 words).

### Text

Headings should be appropriate to the nature of title article. Normally only two categories of headings are used. Major headings should be typed in capital letters and minor in lower case letters (starting with a capital letter) at the left-hand margin. The sub-titles should not be numbered in figures or alphabetically

The text should be written as objectively as possible.

Numerals should be spelt out in full from one to nine (except when referring to a measurement) and when beginning a sentence.

1. Research and experimental manuscripts should follow the usual conventions, as follows:

*Introduction:* Setting forth clearly the aim of the study or the main hypothesis, with reference to previous studies and indicating the method used.

*Material and Methods*

*Result:* Presented in logical sequence in the text, with tables and illustrations. All the results of the tables should not be repeated in the text; the most important results should be emphasized.

*Discussion* should be related to the aims and results of the study.

Care should be taken that language is grammatically correct and fluent, that all relevant information is included, irrelevant details omitted and repetitions, especially from section to section, avoided.

In Case Reports, the sections on “*Material and Methods*” and “*Results*” are replaced by the section “*Clinical Record*”, and all other sections are appropriately shortened.

2. Other papers can be sub-divided, as the authors desire: the use of headings enhances readability.

### References

References cited in the text and given at the end of the manuscript should conform to the Vancouver style. The accuracy of the references is the responsibility of the author. They must be numbered in the order in which they are cited in the text, and should be numbered in Arabic numerals in superscript. References that are cited more than once retain the same number for each citation. The only truly scientifically acceptable references are those of publications that can be consulted. Permission from the source(s) of information for citing their work must be obtained beforehand. All the numbered references in the text should be typed out in detail at the end of the manuscript, in the same numerical order that they appear in the text,

*Journal:* References to an article in a periodical should include the authors’ names (list all authors when six or fewer, when there are more, list only the first three authors and add “et al”), the full title of the article, the name of the cited journal in its usual abbreviated form according to the *Index Medicus*, year of publication, tome or volume number, first and last page numbers in full:

e.g. Jain NK, Chopra KK, Prasad G. Initial and Acquired drug resistance to Isoniazid and Rifampicin and its implications for treatment. *Indian J Tuberc* 2002; **39**: 121-124.

*Book* References to a piece of work (book or monograph) should include the authors names, the title of the piece of work, the place and year of publication:

e.g. Crofton, J. and Douglas, A. *Respiratory Diseases*, 1<sup>st</sup> Edition. Edinburgh: Blackwell Scientific Publications Ltd, 1969.

*Chapter in a book:* Reference to a chapter in a book should include the authors names, the title of the chapter with the word “In” preceding the reference of the work:

e.g. Fraser RS, Muller NL, Colman N, Pare PD. Upper airway obstruction. *In: Fraser RS, Muller NL, Colman N, Pare PD, Bralow L, ed Fraser and Pare's Diagnosis of Diseases of Chest; 4th Ed; Vol III. Philadelphia: W.B. Saunders Co, 1999: pp 2021-2048.*

*Reference to electronic material:* If references are made to electronically published material, as much of the information as for other reference sources should be provided, the html address and the date last accessed.

*Personal communication:* References to personal communications should be given in the text with the name of the individual cited and with his/her consent.

### **Acknowledgements**

Acknowledgements should be brief (not more than 6 lines). Acknowledge only those persons who made substantial contributions to the study and all sources of support in the form of grants.

### **Tables**

Tables should be referred to consecutively in the text, placed after the list of references on separate sheets of paper, and should be numbered in Arabic numerals which are used for reference in the text. A short descriptive title should appear above the table, each column should have a short or abbreviated title. All abbreviations and necessary explanatory notes should be given below the table. The number of tables should be kept to a basic minimum to explain the most significant results.

### **Figures**

*Figures* should be referred to consecutively in the text, placed after the list of references on separate sheets of paper, and should be numbered in Arabic numerals which are used for reference in the text. A short descriptive title should appear above the figure. Figures can be inserted into the Word document for submission or uploaded separately as

image files (.jpg, .gif, or .tif). If this is not possible, good quality (camera ready) prints of the figures must be provided.

*Line drawings* (curves, diagrams, histograms) should be provided in black and white. For optimal clarity, avoid shading.

*Half-tone figures* should be clear and highly contrasted in black and white. Photo- micrographs should have internal scale where appropriate. X-ray films should be carefully made to bring out the details to be illustrated with an overlay indicating the area of importance.

*Illustration:* Legends for photographs should be typed separately with appropriate indication regarding the photograph to which a legend pertains. Photographs (black and white prints) should be clear, glossy and unmounted. Facilities for printing photographs in 4 colours as illustrations in Case Reports are available. Contributors are requested to preferably send colour photographs of their clinical material. Each photograph should carry, on its reverse, the title of the paper, name of the first author and an arrow indicating the top edge of the photograph in pencil. It should be put in an envelope and properly labelled on the outside and attached to the article.

*Patient confidentiality:* Where illustrations show recognisable individuals, consent must be obtained for publication. If not essential to the illustration, authors should indicate where it can be cropped, or mask the eyes.

*Permission to reproduce illustrations or tables* should be obtained from the original publishers and authors, and submitted with the article by email or fax. They should be acknowledged in the legends as follows:

*"Reproduced with the kind permission of (publishers) from (reference)"*

### **Abbreviations and units**

Avoid abbreviations in the title or summary.

All abbreviations or acronyms used in the text must be defined at the first mention, and should be kept to a minimum. Symbols and units of measure must conform to recognized scientific use i.e. SI units.

### LENGTH OF TEXT

**Editorial** text can be up to 500 words with 5 references

**Review articles** are from those especially requested persons, who have acknowledged competence in given subjects. Text can be up to 4500 words, a structured or unstructured summary of maximum 250 words, 10 tables/figures and 50 references. **Leading articles** are by those who have expertise in selected aspect of a subject.

**Original articles** deal with planned studies that have been duly completed and convey definite conclusions from the data presented in the text. Text can be up to 2500 words, a structured summary of maximum 250 words, 7 tables/figures and 35 references. Preliminary communications from research still in progress could be submitted exceptionally, if the topic is important and the interim results could be of interest.

**Short communications** can be of a text up to 1000 words, a summary of 100 words, 2 tables/figures and 10 references.

**Case reports** present problems of unusual clinical interest which have been systematically and fully investigated and where a firm diagnosis has been established with reasonable certainty, or the result of therapeutic management is of significance. Text can be up to 1000 words, a summary of 100 words, 2 tables/figures and 10 references.

Workers in the field of Tuberculosis and

Respiratory Diseases are invited to contribute to the **Radiology Forum** by submitting brief reports of patients with interesting clinical and radiological features for publication. These will be published, provided that:

- (a) the condition is of clinical and radiological interest;
- (b) photographs (10 cm x 8 cm) are of suitable quality for printing;
- (c) the diagnosis in each case has been confirmed;
- (d) the chest radiograph is accompanied by brief clinical account, not exceeding 500 words, and 5 references

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