

Original Article:**Outcome of cases under Revised National Tuberculosis Control Programme at designated microscopy centre of a tertiary level hospital and Medical College at Kanpur, Uttar Pradesh**

Ajay Kumar Verma,¹ Mayank Mishra,² Arpita Singh,³ Sudhir Chaudhri,⁴ Subodh Pandey⁵

¹Department of Pulmonary Medicine, King George's Medical University, Lucknow and

Departments of ²Pulmonary Medicine, ⁵Trauma & Emergency (Pulmonary Medicine),

All India Institute of Medical Sciences (AIIMS), Rishikesh and

Departments of ³Pharmacology, ⁴TB & Respiratory Diseases, GSVM Medical College, Kanpur

ABSTRACT

Background: Study of outcome of patients receiving DOTS under the Revised National Tuberculosis Control Programme (RNTCP) can provide important clues for focussing on the limited resources to further enhance success of DOTS.

Methods: Study of outcomes of patients registered under RNTCP at Ganesh Shankar Vidyarthi Memorial (GSVM) Medical College, Kanpur, Uttar Pradesh (UP), India from February 2006 to March 2007.

Results: The study comprised of 233 cases (130 males), mostly belonging to 31-40 years age group (26.6%) from the socio-economic class IV or below. Category wise patient distribution was 107, 65 and 61 in Category I, II and III respectively. Among new sputum positive cases, 67.6% patients were cured while 13.5% completed treatment. Treatment completion rate of new sputum negative patients was 79.5%. Failure rates in new sputum positive and new sputum negative were 2.7% and 2.6% respectively. Among retreatment cases the cure rates for relapse, treatment after default and failure cases were 50%, 25% and 14.2% respectively.

Conclusion: Certain issues have been identified which include poor sputum conversion as well as cure rates and higher default rates as compared to results quoted by RNTCP. Hence remedial measures like patient education, motivation and counselling can still have a place in improving the compliance and decreasing the default rates.

Key words: Tuberculosis, Treatment, DOTS, Outcome

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INTRODUCTION

Tuberculosis (TB) is a major public health problem. In 2008, there were an estimated 9.4 million incident cases (equivalent to 139 cases per 100000 population) of TB globally.¹ India is the largest TB burden country accounting for one fifth of the global incidence (i.e., about 1.98 million cases are from India). India is 17th among 22 high burden countries in terms of TB incidence rate.² World Health Organization (WHO) declared TB to be a global emergency in the year 1993.³ The DOTS strategy is believed to be the most valuable strategy for TB control. To combat this overwhelming problem, the Government of India also piloted and then expanded this DOTS strategy under the

RNTCP.⁴ It has now achieved 100% geographical coverage of the country under DOTS in March 2006.

The involvement of Medical Colleges in RNTCP primarily include service delivery of RNTCP through quality assurance net-work group; training and teaching about RNTCP; advocacy regarding RNTCP by sensitization and training; and operational research.^{5,6} As sparse published data are available on this subject, we studied the outcome of patients registered under RNTCP at our Medical College tertiary care teaching hospital.

MATERIAL AND METHODS

The patients were enrolled between February 2006 to March 2007 from the laboratory register

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Corresponding Author: Dr Mayank Mishra, Assistant Professor, Department of Pulmonary Medicine, All India Institute of Medical Sciences (AIIMS), Rishikesh, India. **e-mail:** virgodrmayank@gmail.com

of the Designated Microscopy Centre (DMC) located at Department of Tuberculosis and Respiratory Diseases, Ganesh Sankar Vidyarthi Memorial (GSVM) Medical College, Kanpur, Uttar Pradesh (UP), India. The institutional Ethical Committee accorded waiver and cleared this study. Standard methods of diagnosis, enrollment, treatment and referral under the RNTCP were followed.

Of the 2372 chest symptomatic patients who attended the various out-patient departments (OPDs) of our Medical College, sputum smears of 626 (26.4%) were positive for acid-fast bacilli (AFB). Out of these 626 patients, 344 were prescribed DOTS while 282 patients (45%) were 'initial defaulters'. Of these 344 patients, 63 were started DOTS at our DOT centre while 281 were referred for DOTS to other centres at their place

of domicile. Among these 281 patients, 190 belonged to Kanpur district and 91 patients were from outside Kanpur. One hundred and seventy patients who were residents in the catchment area of the Medical College, were diagnosed to have TB elsewhere and were referred to our Medical College DOT centre. Overall 233 cases were registered for DOTS at our Medical college.

In the present study, only patients who received treatment at our Medical College DOT centre (n=233) were followed-up. This included two types of patients : (i) those who were diagnosed at our centre (n=63); and (ii) those who were diagnosed elsewhere and transferred in to our centre during the study period (n=170). All patients who were transferred out after being registered at our medical college DOT centre were not followed-up in this study (n=281). Also, 20 patients who

Table 1: Outcome of different types of cases

Type of patient	Cured %	Treatment completed* %	Treatment defaulter† %	Failed %
New smear-positive (n=74) (Out of total 81 new smear-positive, 7 patients were transferred out during study duration) (1 patient died)	67.6	13.5	8.1	2.7
New smear-negative and extra-pulmonary (n=78) (Out of total 87 new smear-negative and extra-pulmonary cases, 9 patients transferred out during study duration)	NA	79.5	18	2.7
Re-treatment cases (Relapse + TAD + Failure + Others) (n=60)	34	45	15	10
Relapse (n=20)	50	40	5	5
TAD (n=20) (Out of total 22 TAD patients, 2 patients transferred out during study duration; 1 patient died)	25	40	10	20
Treatment failure (n= 7) (Out of total 9 failure patients, 2 patient transferred out during study duration)	14.2	42.9	14.3	28.6
Others (n=13) (1 patient died)	NA	61.5	23.1	7.7

* Patients who completed treatment from the medical college DOT centre but did not produce sputum at end of treatment.

† Includes patients who willingly switched over to private sector at 1 month or more into the continuation phase but completed their treatment, as enquired by TBHV=Tuberculosis Health Visitor
DOT=Directly Observed Treatment; NA = not applicable; TAD = treatment after default

were transferred out during the course of the study period were also not followed up (Table 1).

RESULTS

During the study period, 233 cases were registered under RNTCP at our DMC and DOT centre, inclusive of cases diagnosed here and those that were referred here from outside. Most of the patients were in the 31-40 years age group (62/233; 26.6%). There were 130 (55.8%) males. According to modified Kuppuswamy scale,^{5,6} 39% patients belonged to socio-economic class IV (upper lower) followed by Class V (lower) (32%); 81 (34.8%) were illiterate.

Out of 135 sputum-positive cases, 81 (60%) were 'new' cases. Of these,⁷ were transferred out during the course of the study and 74 patients were followed-up. Among 'sputum smear-negative' and 'extra-pulmonary' cases (n=26; 26.5%) patients

were categorized to receive Category I treatment; 11 (11.2%) received Category II treatment and 61 (62.2%) received Category III treatment (Figure 1).

Maximum number of our patients (47.7%) were referred by general practitioners. The mean time lag between appearance of symptoms and first consultation by patients was 8.5 (\pm 9 weeks).

Only 17.7% patients sought medical attention within 1 week of onset of symptoms; 32% patients took action in 1-3 weeks; 28.4% took 3 weeks to 3 months; while 22% patients took medical help after three months. There was no gender difference in this respect. Only 71.7% of patients in the present study consulted health care providers within 1 week of onset of symptoms. The time lag between onset of symptoms and consulting health care providers was lesser in urban patients

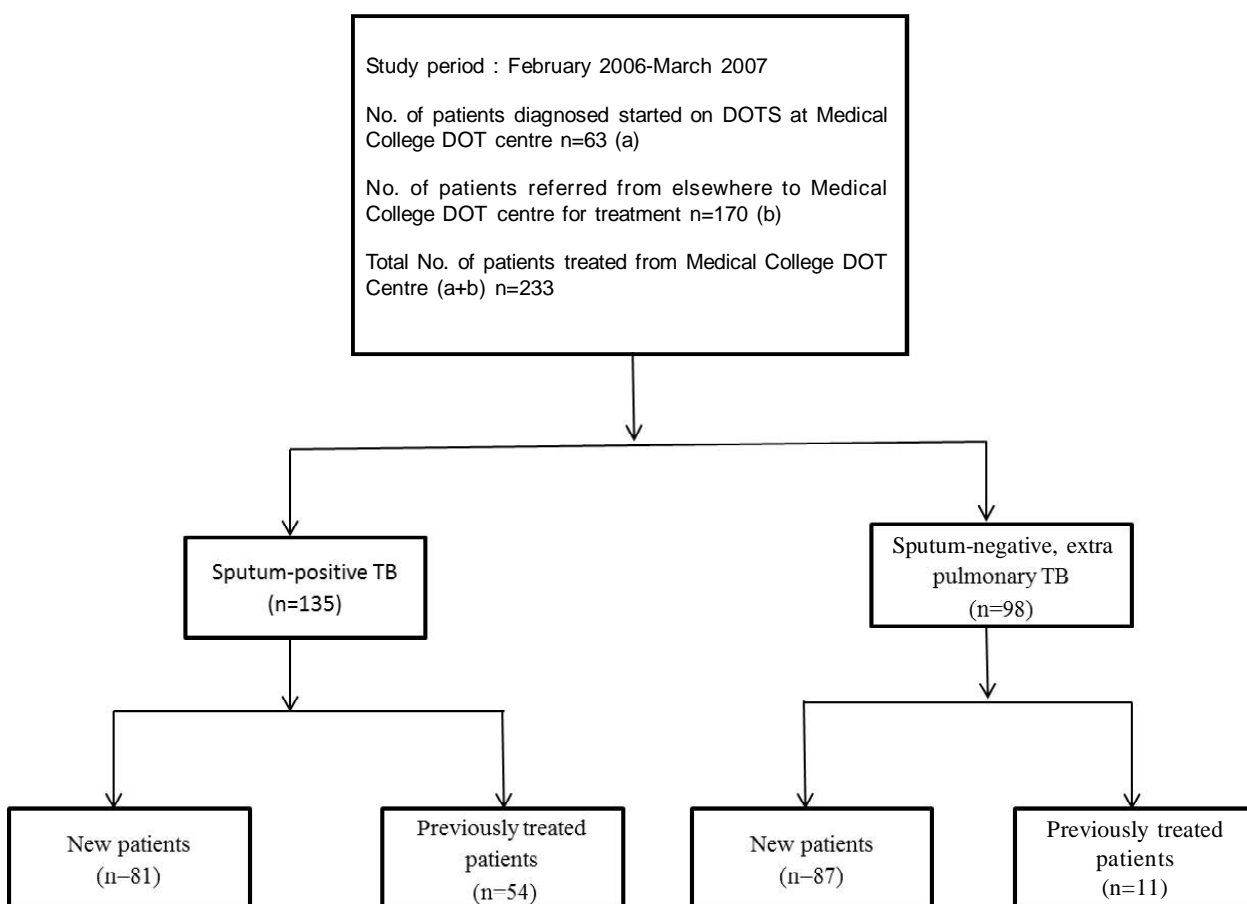


Figure 1: Categorization details of 233 patients with TB treated from Medical College DOT centre
TB=tuberculosis; DOT centre = Directly Observed Treatment centre

(7.95 ± 9.4) compared with rural patients (9.9 ± 11.4). However, this difference did not attain statistical significance ($p=0.1$). In our study, among 64 sputum positive re-treatment patients TAD were 45.31%, while relapse cases were 35.9% and failure cases were 18.8%.

History of close contact with known case of pulmonary TB was present in 30.5% cases. The prevalence of diabetes mellitus among patients taking treatment at our DOT Centre was 3.3%. Four patients were human immunodeficiency virus (HIV) seropositive. All of them were males; 3 had pulmonary and 1 patient had extra-pulmonary TB. A large number (73.8%) of patients were addicted to one or more intoxicants. Tobacco abuse (tobacco chewers 74%; tobacco smokers 69%) was the most common of these. During treatment, most common side effect was gastro-intestinal upset observed in 16.3% cases.

Among new sputum-positive cases that were followed-up ($n=74$), 67.6% patients were cured, 10/74 (13.5%) completed treatment (but were not producing sputum at the end of treatment). Treatment completion rate among new sputum-negative patients was 79.5%. Treatment failure was observed in 2.7% of new sputum-positive and 2.6% of new sputum-negative patients. Among previously treated sputum-positive cases, the cure rates were 50% for relapse patients, 25% for treatment after default (TAD) and 14.2% for treatment failure cases. The respective treatment completion rates were 40%.

During the intensive phase of treatment, 24 (10.3%) patients had defaulted. Of these, 8 (3.43%) patients could be brought back to treatment by defaulter action while 16 (6.9%) patients could not (Table 2A). A majority of patients who interrupted the treatment [51 (89.5%)] attributed a "feel good sensation" as the prime cause. 45%

Table 2A: Default patterns

	During intensive phase (n=233) No. (%)	During continuation phase (n=217) No. (%)	Total no. of defaulters
No. of patients who defaulted	24 (10.3)	39 (16.7)	–
No. of patients brought back by defaulter action	8 (3.4)	16 (6.9)	–
No. of patients who could not be brought back	16 (6.9) (defaulted at < 2 months of treatment initiation)	17+6*=23 (9.9) (defaulted within a month of initiation of continuation phase)	39 (16.7)

*These six patients willingly switched over to private sector

Table 2B: Reasons for interruption of treatment

Reason for treatment interruption	% patients
Feel good factor	89.5
Lost faith in treatment	45
Side effects	31.6
Went out of station	35.1

patients lost faith in treatment; adverse effects were responsible in 31.6% cases; and 35.1% patients defaulted treatment because they were moving out of their place of domicile (Table 2B).

DISCUSSION

Of the 344 patients diagnosed to have TB, only 63 were started on DOTS at the Medical College DOT centre while 281 were referred to their place of domicile for DOTS. This is likely to reflect the fact that tertiary care teaching hospital of the Medical College is visited by patients not only from Kanpur, but also from neighbouring districts and far flung areas also.

In our study, new smear-positives constituted 60% of all smear-positive cases. This is almost similar to national figure of 58%⁸ observed under RNTCP.⁸ The high number of sputum-negative and extrapulmonary cases receiving Category I regimen reflects the fact that many seriously ill patients visit Medical College teaching hospital as expert opinion is available here.

These observations suggest that only few patients seek health care early for symptoms of TB. Efforts are required to educate the patients and health care providers to facilitate early diagnosis of TB.

Urban patients took relatively early action in seeking medical help compared to rural patients ($p=0.1$). In a nutshell, urban and rural patients were not very different with regard to the time lag between appearance of symptoms and taking action to seek medical help is concerned. Urban patients are likely to access health services early due to better transport facility and information. In our study the fact that rural patients were not far behind in this respect reflects the wide-spread availability of RNTCP services and a high awareness regarding these services among patients in rural areas.

Out of 233 patients receiving DOTS from our Medical College DOT centre, a substantial 209 (89.7%) patients did not default treatment during intensive phase. Of the 24 (10.3%) patients who

defaulted, 8 (8.4%) could be brought back to treatment by defaulter action. During continuation phase, 39 (16.7%), defaulted of whom 16 (6.9%) could be brought back to treatment by defaulter action. These observations suggest that there is a need to strengthen this aspect further under programme conditions to treatment by defaulter action.

Among new sputum positive cases, 67.7% patients were cured, 13.5% patients completed treatment, while 2.7% patients failed on treatment. According to RNTCP status report 2007,⁸ the national average cure rate among new sputum positive cases was 83.3% while in UP state it was 83.8%.⁷ The cure rate observed in the present study (13.5%) is lower but treatment completion rate is more than that observed at national level (2.3%) and at UP state level (3%). Further, treatment success rate of our patients is (79.9%) is comparable to the national average of 85.6% and UP state average of 86.8%.⁸ Six of the 74 (8.1%) new smear-positive patients who were labelled 'treatment defaulters' had willingly switched over to the private sector for treatment. In this regard, the already-existing problem of inadequate public-private partnership which poses significant challenges in the successful implementation of RNTCP should be re-emphasized. The private health sector, frequently preferred by the patients as a first choice, needs to be integrally involved in RNTCP on a priority basis.^{9,10} In our study, the failure rate among new sputum positive cases was 2.7% similar to the observation at country level (2.4%) and at UP state level (1.2%).⁷

In the present study, treatment completion rate of new sputum negative patients was 79.5% which was similar to observations at country level (86.7%) and UP state level (88.3%).⁷ But, more (2.6%) of new sputum-negative patients failed on treatment. Comparable figures at country level and UP state level were 0.8% and 0.6% respectively.⁷

In our study, among re-treatment cases the cure rate was 34.04% (country 61.7%, UP 69.0%).⁷ The respective treatment success rate was 72.33% in our study (country 68.7%, UP 76.1%).⁷ This suggests that possibly many patients do not turn up for sputum examination at the end of treatment. The failure rate in our study among re-treatment cases was 14.9% which was more than the national figure, but similar to the situation in UP (13.4%).⁷

In our study, over all default rate (all cases) was found to be 16.73% (in intensive phase it was 6.86% while in continuation phase it was 9.87%). According to RNTCP status report 2007, the defaulter rate in new sputum smear positive patients was 6.9% at country level and that in UP it was 7.9%. In new smear negative cases at country level it was 8.5% and at UP state level it was 8.9%. Among new extrapulmonary cases defaulter rate was 5.6 % and 4.8% at country level and UP state level respectively.⁷ In general default rate was high in our study.

Our study identifies issues which include poor sputum conversion as well as cure rates and higher default rates as compared to results quoted by RNTCP. Moreover, a feel-good factor, loss of faith in treatment, side effects due to anti-tubercular drugs and patient going out of station have been identified as important causes for treatment interruption. Hence, addressing these factors and tak-

ing remedial measures like patient education, motivation and counseling certainly have a place in improving the compliance and decreasing the default rates.

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