

## Short Communication

### SPUTUM EXAMINATION AT 2-MONTHS INTO CONTINUATION PHASE - HOW MUCH DOES IT CONTRIBUTE TO DEFINE TREATMENT OUTCOME?

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#### Summary

**Objective:** To assess the usefulness of sputum examination at 2-months into Continuation Phase (CP) to declare treatment outcome.

**Methodology:** It is a retrospective study conducted in one tuberculosis unit, Tiruvallur district of Tamilnadu among smear positive patients treated with Category I and Category II regimens from May, 1999 – December, 2003.

**Results:** Sputum was collected at 2-months into CP from 70% of 1551 Category I and 74% of 292 Category II patients declared cure, failed or treatment completed. Result at 2-months CP was used for giving outcome in 112 (10.3%) of 1088 Category I patients and 37 (17%) of 217 Category II patients.

**Conclusion:** In practice, sputum needs to be collected for 7.8% of the patients with smear positive at the end of Intensive Phase. By doing so, there will be a delay of 1 month for 3.6% of the patients in declaring 'failure'. By deferring the sputum examination at 2 months into CP, workload of laboratory technicians can be reduced by about 30%. [*Indian J Tuberc* 2006; 53:37-39]

**Key words:** Tuberculosis, treatment outcome, intensive phase and continuation phase

## BACKGROUND

Sputum microscopy for acid-fast bacilli (AFB) is an accepted tool to diagnose and monitor the progress of pulmonary tuberculosis cases globally<sup>1</sup>. For monitoring progress, sputa are examined at the end of intensive phase (IP), 2-months into the continuation phase (CP) and end of treatment<sup>2</sup>. Sputum smear result at 2-months of intensive phase is to decide the need for extension of IP or going on to CP. Smear at 2-months into CP, helps to identify failure cases and is also useful to declare a patient 'cured' in case smear at end of IP is positive. End of the treatment smear is necessary to give treatment outcome. 'Cure' is defined as 'initially smear positive patient having negative smear during follow up on two occasions out of which one is at the end of treatment'. The present paper reports on the utility of sputum examination at 2-months into CP to decide the treatment outcome among sputum positive patients treated with Category I (CAT I) and Category II (CAT II) regimens.

We undertook a retrospective analysis of patients treated with CAT I (2EHRZ<sub>3</sub>/4RH<sub>3</sub>) and CAT II (2SHREZ<sub>3</sub>/1HREZ<sub>3</sub>/5RHE<sub>3</sub>)<sup>2</sup> regimens of Directly Observed Treatment Short-course (DOTS) strategy from May 1999 to December 2003 from one

tuberculosis unit (TU) area of Tiruvallur district, Tamilnadu.

## RESULTS

Among 1893 patients admitted to CAT I treatment, 1447 (76 %) were declared 'cured', 257 (14%) 'defaulted', 85 (4%) 'died', 94 (5%) 'failed' and 10 cases 'treatment completed'. Corresponding figures for 575 CAT II patients were 237 (41%), 242 (42%), 41 (7%), 52 (9%), and 3, respectively.

Of these 1893 CAT I patients, 1551 were declared 'cured', 'failure' or 'treatment completed' and were eligible for sputum collection at 2-months into CP. Sputum was collected from 1088 (70%) patients (Table). Of these, 1012 (93.0%) specimens were negative at 2-months into CP, of which 955 (94.4%) were not useful to declare the outcome as 'cure', as these patients were sputum smear negative at end of IP and end of treatment. For the remaining 57 (5.6%) patients, the sputum was negative at 2-months into CP and was useful for declaring the outcome as 'cure' as these patients were sputum positive at the end of IP. Among 76 patients who were positive at 2-months into CP, 21 were negative at the end of IP and end of treatment for declaring as 'cure'; hence 2-months CP result was of no

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**Table:** Utilization of sputum result of 2-month into CP for treatment outcome among category I and II patients treated under DOTS

	CAT I		CAT II		Total	
	No.	%	No.	%	No.	%
<b>Total admitted</b>	<b>1893</b>		<b>575</b>		<b>2468</b>	
Eligible for sputum collection at 2m CP ('cure', 'failure' and 'treatment completed')	1551		292		1843	
<b>2m CP specimen collected</b>	<b>1088</b>	<b>70.1</b>	<b>217</b>	<b>74.3</b>	<b>1305</b>	<b>70.8</b>
<b>2m CP - smear negative</b>	<b>1012</b>	<b>93.0</b>	<b>177</b>	<b>81.6</b>	<b>1189</b>	<b>91.1</b>
Used for treatment outcome 'cure'-(a) (End of IP smear positive)	57		5		62	
Not used treatment out come 'cure' (End of IP – smear negative)	955		172		1127	
<b>2m CP - smear positive</b>	<b>76</b>	<b>7.0</b>	<b>40</b>	<b>18.4</b>	<b>116</b>	<b>8.9</b>
Used for treatment outcome 'failure'-(b) (End of IP negative and subsequent positive)	29		18		47	
Used for treatment outcome 'failure'-(c) (End IP and subsequent positive)	26		14		40	
Not used treatment outcome 'cure' (End of IP and end of treatment negative)	21		8		29	
<b>2m CP - used for treatment outcome- (a+b+c)</b>	<b>112</b>	<b>10.3</b>	<b>37</b>	<b>17.1</b>	<b>149</b>	<b>11.4</b>

consequence. For the remaining 55 (72.4%) who were subsequently positive, the 2-months CP result was useful to declare them as 'failure'. Overall sputum result at 2-months into CP was useful for 112 (10%) of 1088. Out of 112 patients, sputum was negative for 29 patients at the end of IP and positive at 2-months into CP. These patients will be declared as 'failure' if they continue to be sputum positive at 5<sup>th</sup> month also. If sputum was not examined at 2 months into CP, these patients would have been declared as 'failure' at 6 months, with a delay of one month. Smear results at 2-months into CP was really useful to give outcome only for the remaining 83 (7.6%) of 1088 patients who were smear positive at the end of IP.

Similarly, among 575 CAT II patients registered, 292 were eligible for collection at 2-

months into CP and sputum was collected from 217 (74.3%) (Table). One hundred and seventy seven patients were smear negative at 2-months into CP but only 3% (5 of 177) of the result was utilized for declaring the outcome as 'cure'. Among 40 patients who were positive at 2-months into CP, 32 (80%) was useful for declaring the outcome as 'failure'. Overall only 17% (37 of 217) of the smear result at 2-months into CP was utilized for outcome. Eighteen of 37 patients with smear negative at the end of IP would have been declared 'failure' with a delay of 1 month if sputum was not examined at 2-months into CP. Smear results at 2-months into CP was useful to give outcome only for the remaining 19 (8.8%) of 217 patients who were smear positive at the end of IP.

Significantly more patients were absent for

sputum examination at 2-months into CP among patients near to non-microscopy centre (34%; 112 of 326) compared to microscopy centre (29%; 351 of 1225) ( $P < 0.05$ ); aged 45 years or more (33%; 229 of 691 vs. 27%; 234 of 860:  $P < 0.05$ ) and alcoholics (35%; 173 of 493 vs. 27%; 267 of 1003:  $P < 0.001$ ). In total, for CAT I and CAT II combined, only for 11.4% (149 of 1305) of patients, the result at 2-months into CP was used for declaring the outcome. Among the 149 patients, 47 (3.6%) would have been declared failure with a delay of 1 month had sputum not been examined at 2-months into CP. Sputum need to be examined only for the remaining 102 (7.8%) patients with positive smear at the end of IP.

## DISCUSSION

Our finding indicates that sputum results at 2-months into CP has been useful mainly for patients who were smear positive at the end of IP, to define the treatment outcome. Sputum collection at 2-months into CP is done for patients who are initially smear positive. Since continuation of treatment in the CP with the same drugs is not dependent on the results of 2-months into CP, DOT provider is likely to miss to collect the specimens. In our study, sputum was not collected for 30% of patients at 2-months into CP among eligible CAT I patients. Non-collection of sputum was associated with type of centre, alcoholism and age of the patient. However, this has not influenced decision of treatment outcome. A small proportion (3.6%) of patients (CAT I and CAT II) for whom sputum was negative at the end of IP but found to be positive at 2-months into CP, could be the group for whom there is likelihood of delay of 1 month to declare 'failure'. If patients visit the health facility for the sputum examination in the 2-months into CP, they may have an added advantage of being motivated by the medical officer. But if we insist on the sputum examination at the stage, the DOT provider may not give the remaining CP drugs till sputum is given and the results become available.

Zhao et al<sup>3,4</sup> reported that end of IP sputum results are predictors of outcome and sputum

conversion during the third month of treatment is an important predictor of treatment success; failure to convert predicts treatment failure. Wilkinson et al<sup>5</sup> reported that with CAT I treatment in the absence of initial drug resistance, rifampicin-based short course chemotherapy results in microbiological cure of almost all patients who complete treatment, thus making routine follow-up smear examinations a low priority. Follow-up smear examination may remain necessary in countries with high rates of drug resistance or in persons with an unfavourable clinical course.

**Our findings also showed that the smear results at 2-months into CP was required only for patients (CAT I; 7.6% and CAT II; 8.8%), who were smear positive at the end of IP. For the patients who were likely to be positive at 2-months into CP, there would be a delay of 1 month to declare them 'failure' as sputum is examined at the end of treatment. Of 3 occasions during follow up, if we cut down sputum examination at 2-months into CP, there will be about 30% reduction in the work load of sputum examination during follow up. Based on these findings, resources and time and energy of workers and patients can be saved by deferring routine sputum examination at 2-months into CP for patients with smear negative at the end of IP.**

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