

DIAGNOSIS OF TUBERCULOSIS UNDER RNTCP : EXAMINATION OF TWO OR THREE SPUTUM SPECIMENS

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Summary: The Revised National Tuberculosis Control Programme (RNTCP) recommends examination of 3 sputum smears for diagnosis. This may not be practicable under all conditions, specially in difficult areas. It further adds to the cost of diagnosis and causes inconvenience to patients. In order to study the diagnostic yield of examining only two smears and the additional yield by the third smear, a retrospective study of the data from the RNTCP area of the LRS Institute was carried out for the years 1998 and 1999.

In 1998, in all 719 sputum positive patients were diagnosed out of 3738 new chest symptomatics examined (19.2%) and in 1999, there were 1044 sputum positive patients from 4189 new chest symptomatics examined (24.9%). The diagnostic yield of a single sputum specimen examined is insufficient under field conditions, especially where the sputum positivity is low. However, sputum positivity of two or more sputum smears did not affect diagnostic yield. Further, of the three sputum smears examined (spot, early morning, spot), the early morning specimen had the best result.

It is concluded that under field conditions, two sputum smears (one of which is early morning) is as effective as three smears for screening of chest symptomatics. Reduction in the number of smears to two is expected to reduce cost (both for patients as well as health care provider) without compromising quality. However, before changing national programme policy, more studies in different situations (rural areas, difficult areas, etc.) are recommended

Key words : Tuberculosis programme conditions, Sputum diagnosis, Case yield from different sputum specimens

INTRODUCTION

Ever since sputum smear examination was made the specific tool for diagnosing tuberculosis, scientists have investigated the additional case yield from examination of multiple successive sputum specimens'. Studies from NTI^{2,3}, Bangalore examined this aspect with upto eight successive smears tested amongst chest symptomatics who had an abnormal chest x-ray. It was observed that the first two smear examinations were sufficient to detect 85 per cent of the total smear positive patients. In the NTI study, the overall smear positivity in the group was around 27 per cent. Accordingly, in the National Tuberculosis Programme, the recommendation regarding number of specimens was limited to two sputum smear examinations for case-finding under programme conditions.

In the Revised National Tuberculosis Control Programme, under implementation since 1993, the diagnosis of pulmonary tuberculosis is also primarily

sputum based in accordance with the WHO⁴ and IUALD⁵ guidelines. Each chest symptomatic is required to give three sputum specimens (first spot, second early morning and third spot specimen). To facilitate this requirement, sputum testing centres have been provided, one per 1,00,000 population in the community, and these microscopy centres have been fully upgraded in terms of equipment and well trained staff. However, in a country which has nearly one-third of the global burden of the disease, the number of sputum smear examinations required to be done for detecting all the tuberculosis patients would be nearly 30 million per year (one million sputum positive 'incidence' cases, 10 percent positivity rate from attending symptomatics and three smears per symptomatic). With the increasing threat of TB/HIV co-infection, the burden of disease would increase further and, accordingly, the number of smears required to be done would also increase. Studies conducted by the IUATLD in Tanzania⁶ have shown that successive yield of smears amongst positive cases was: 83.4 per cent from the first

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specimen, and increase of 12.2 per cent from the second and 4.4 from the third. Other studies in Malawi also yielded similar results^{7,9}. These results suggest that under field conditions, the third smear is not likely to yield much. When the examination load is heavy and resources are limited, the policy could allow doing only two smears instead of three.

OBJECTIVE

In order to test the above assumption, a study was conducted in the RNTCP demonstration area of the LRS Institute of TB & Allied Diseases, New Delhi to determine the value of the third sputum smear in case-finding amongst chest symptomatics attending the RNTCP microscopy centres under field conditions.

MATERIAL AND METHODS

The LRS Institute of TB & Allied Disease is implementing the RNTCP as per national guidelines in a population of around one million spread out in the southern part of Delhi. Ten DOT-cum-Microscopy Centres have been established to provide diagnosis and treatment facilities. Each of these centres has one Microscopist and one TB Health Visitor. The attending symptomatic is required to give three sputum smears (first spot, second early morning, third spot specimen) over two consecutive days for case-finding.

A retrospective analysis of the data in the Laboratory Registers of all the 10 Microscopy Centres was carried out for the years 1998 and 1999

in order to determine (i) the number of chest symptomatics who attended, (ii) the number of symptomatics who had all the three smears positive and various combinations of positivity i.e. only first smear positive, only second smear positive, only third smear positive, and first and second, first and third and second and third smears positive and (iii) the percentage of positivity of the first specimen, incremental yield of the second specimen, and incremental yield of the third specimen.

RESULTS

In 1998, a total of 3738 new chest symptomatics were registered of whom 719(19.2%) were sputum positive. For the year 1999, the total new chest symptomatics examined were 4189 of whom 1044 (24.9%) were sputum positive. The past treatment history of the newly discovered sputum positives was not a part of the study. The detailed results from successive three smears examined for all the sputum positives for both the years are given in Table i. The analysis of the data showed that reliance on the first specimen (spot) could detect 86.5 per cent (6227 719) of the sputum positive patients in 1998 and 90.5 per cent (945/1044) in 1999. In addition, if the second specimen morning was also taken into consideration then 99.4 per cent (715/719) of the patients could be detected in 1998 and 99.6 per cent (1040/1044) in 1999. The incremental yield of the third specimen (spot) smear was less than one per cent in both the years (Table 1).

Table 2 shows the comparison between 1 st spot specimen, 2nd early morning specimen and 3rd spot specimen in terms of case yield. The first spot

Table 1: Distribution of smear positives among symptomatics in successive specimens and years

Year	1998		1999	
	No.	%	No.	%
Mew chest symptomatics	3738	0	4189	(-)
Total sputum positives detected	719	19	1044	25
Positive by all 3 specimens	565	79	824	79
Positive by 1st Specimen (spot)	622	86.5	945	90.5
2nd Specimen (morning)	708	98.5	1006	96.4
3rd Specimen (spot)	597	83.0	897	85.9
Additional positive by				
2nd Specimen (morning)	93	12.9	95	9.1
3rd Specimen (spot)	4	0.6	4	0.4

Table 2: Comparison of early morning specimen with successive spot specimens

Year	No. of smear +ves	Only 1st	Only 2nd	Only 3rd	Comparison	
		(spot) +ve	(morning) +ve	(spot) +ve	1st vs 2nd	2nd vs 3rd
1998	719	622/719 (86.5%)	708/719 (98.5%)	597/719 (83.0%)	PO.001	PO.001
1999	1044	945/1044 (90.5%)	1006/1044 (96.4%)	897/1044 (85.9%)	PO.001	P<0.001

specimen has the case yield of 86 to 90 percent. The second smear examination (which is an early morning specimen) takes the yield to over 98%.

purposes under field conditions where it is preferable to avail of every opportunity to examine sputum.

DISCUSSION

The third sputum examination, as recommended by the RNTCP adds not only to the laboratory workload but also to the cost of diagnosis, both for patients as well as for the health system. The present analysis of data suggests that :

iii) Of the three sputum specimens, the early morning one gave the best results as compared to the other two spot specimens. If only the early morning specimen were required for testing, then approximately 98.5 percent of the patients could be detected in 1998 and 96.4 percent in 1999. This is higher yield than the results with the two spot specimens (1st & 3rd) and the difference is statistically significant. (P<0.001) (Table 3).

i) If the overall sputum positivity content of a laboratory workload is around 25 percent, then 90.5 per cent of the sputum positive patients can be detected by the first spot sputum specimen. This yield gets reduced to 86.5 if the positivity content of laboratory workload is around 19 percent. This difference is statistically significant (P <0.05) and indicates that with lower overall sputum positivity in the workload the value of a single spot specimen for reaching diagnosis gets reduced. Hence, in situations where sputum positivity among those examined is as low as 5 to 10 per cent, the yield of a single spot sputum specimen for diagnosis would be considerably less and cannot be depended upon in field conditions.

Table 3: Comparison of morning with spot specimens according to diagnostic yield and year

Year	Total smear +ives	Positives by spot specimens		Positives by morning specimens (spot)
		(1st and 3rd smears)	4	
1988	719	622	4	708
(19.2)	(100.0)	(87.1)		(98.5)
1999	1044	945	4	1006
(24.9)	(100.0)	(90.9)		(96.4)

Figures in parentheses are percentages

ii) However, overall sputum positivity content does not affect the detection value of the test if two specimens, one of which is an overnight sample, are examined. In the comparison, for both years, though there was a significant difference in positivity content, 2 smears (spot plus early morning) could detect nearly 100% of the patients. Thus, two sputum specimens, one of which is overnight, may be sufficient and are dependable for diagnostic

Thus, under routine conditions, 2 sputum smears (one of which is early morning) can be recommended in place of 3 smears for screening chest symptomatics. The reduction in workload may give more time to an overburdened laboratory for improving quality of sputum microscopy. In addition, there would be saving in the cost of laboratory

consumables. It has been estimated that each smear examination costs about Rs. 7 in LRS Institute laboratory. The saving at national level would be enormous if the cost of health infrastructure, technicians' time and patients' lost time are added. However, before a change in national programme strategy is considered, further studies in different situations in the country are needed.

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