

Why Should We Concentrate?

N.Murugan,¹ A.Sundararajaperumal², A.Chitrakumar³, N.Meenakshi⁴.

Associate Professor of Thoracic Medicine, Government Vellore Medical College¹

Associate Professor of Thoracic Medicine, Madras Medical College^{2*}

Professor of Thoracic Medicine, Madras Medical College³

Professor of Thoracic Medicine, Madras Medical College⁴

Corresponding author: A.Sundararajaperumal

Abstract: Background: Sputum smear microscopy is the backbone of the Revised National Tuberculosis Control Programme. It is an easy, safe and effective diagnostic method for pulmonary tuberculosis. But, it involves three patient visits to the hospital. We encounter a lot of initial defaulters and, therefore, we need a method to decrease the patient visits without compromising on the results. We compared spot concentrated AFB smear versus spot and home RNTCP AFB smear, and we found the additional diagnostic yield by concentrating spot and home RNTCP specimen and analyzed the results.

Materials And Methods: This is a prospective study of 600 tuberculosis suspects who came to the Outpatient Department of the Institute of Thoracic Medicine, Chennai. Persons who were not able to bring out sputum and individuals with hemoptysis were excluded from the study. All consenting participants were asked to give good-quality spot and early morning sputum of about 5 mL, each of which was divided into two equal parts. Part 1 was subjected to concentration by the liquid ammonia technique and stained with Ziehl Nielsen stain. Part 2 was smeared as per the regular RNTCP technique.

Results: The results of 600 tuberculosis suspects were analyzed. Spot RNTCP AFB smear diagnosed 49 cases. Home RNTCP AFB smear, Spot concentrated AFB smear and Home Concentrated AFB smear diagnosed 54 cases each. It was found that Spot concentrated AFB smear is as good as Home RNTCP AFB smear. There is no difference between the Spot concentrated AFB smear and the Home concentrated AFB Smear results. Comparing Spot RNTCP AFB smear and Spot concentrated AFB smear, there was a statistical association ($P < 0.001$), which was highly significant. **Clinical Implication:** In diagnosing pulmonary tuberculosis cases, Spot concentrated AFB smear alone itself is as good as RNTCP spot and Home specimens combined. The number of visits required for diagnosing and initiating treatment is reduced. The problem of initial defaulters is also reduced.

Keywords: Pulmonary tuberculosis, concentrated AFB smear, initial defaulters, sensitivity of smear.

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I. Introduction:

From the well established time tried smear microscopy to GeneXpert, there is steady development of demonstrative strategies for tuberculosis. Smear microscopy by temperance of its effortlessness, accessibility, cost adequacy, specificity and its capacity to recognize infectious patients is as yet pertinent, particularly in low salary countries.¹ Yet the issue with smear microscopy is its fluctuating sensitivity, which relies on various elements including legitimate sputum gathering, arrangement of smears, great recolouring system, watchful examination of smears and the accessibility of good microscopy.¹ Attributable to the multifaceted nature and, here and there lab specialists tend to evade sputum examination.¹ For a half likelihood of finding a solitary AFB in 100 microscopy fields around 5000 AFB must be available per ml of sputum.² Subsequently the sensitivity of this method is just 30-70% of culture. In HIV patients and kids who more often than not have bring down convergence of AFB in the sputum, the affectability still drops further.³ So expanding the affectability of TB testing is very much needed.

Work in Malawi has demonstrated that a significant(15%) extent of TB patients drop out before the outcomes were conveyed to them.⁴ Gathering numerous sputum tests increment the remaining task at hand which can decrease the exactness of results. Recurrent visit of the patient will add to their expense. Building a technique which perfects the execution of smear microscopy, in the meantime decreases the quantity of patient visits will have an immense general well being sway. After various examinations focusing on the unnecessary quality of doing the third smear,⁵ we were interested to know whether it could in any case be diminished to a solitary smear, without trading off the efficiency of the outcomes acquired.

Objective

- 1.To compare a single spot concentrated AFB smear versus 2 direct sputum AFB smears done regularly in RNTCP(Spot & Early morning specimen).
- 2.To find the additional yield in concentrating both the spot and early morning sputum specimen.

II. Materials And Methods

Study Centre-Outpatient department of Thoracic Medicine, Chetpet, RGGGH, Chennai, Tamilnadu.

Duration Of The Study-February2011-October 2011

STUDY DESIGN-Prospective observational study

Sample Size-600

Inclusion Criteria-Pulmonary tuberculosis suspects⁶

EXCLUSION CRITERIA-

Persons with haemoptysis

Persons unable to bring out sputum

Persons with prior history of tuberculosis

600 qualified members were selected. They were told how to give a decent quality sputum. 5ml of spot and 5ml of early morning sample were gathered. Each sample was partitioned pretty much similarly and subjected to direct smear and concentration technique. The concentration technique utilized in this examination was portrayed by Vasanthakumari et al.⁷Direct smears were finished by Ziehl Neelson technique.⁶So from a single patient 4 smears were done(2 concentrated and 2 direct smears).

The grading of the smears was finished by RNTCP technique. The direct smears and the concentrated smears were perused by 2 isolate lab specialists. They were twofold blinded and cross blinded to results, to keep them from affecting the outcomes. The experience of the lab professionals were 5 and 3 years individually. The inter and intra reader reliability was surveyed by the count of kappa co-efficient which estimates the degree to which the after effects of the two tests differ when perused by 2 free perusers. A kappa esteem somewhere in the range of 0.80 and 1 means relatively culminate agreement.⁵ External and interior quality appraisal was kept up amid the time of study.

III. Results

Demography

Total number of participants was 600. Among them 407 were males and 193 were females. Total number of pulmonary tuberculosis cases by direct smear method was 77. Total number of pulmonary tuberculosis cases by concentrated smear method was 79. During the diagnostic pathway 5 participants dropped out of the study on day 2. Among them one participant was sputum spot smear positive by both direct and concentration method. Since, from a single participant 4 smears were done, drop outs being 5, (4 *595=2390 smears) were analyzed.

	Male	Female
Total participants(600)	407(68%)	193(32%)

Table (5).Table showing the number of male and female participants in the study

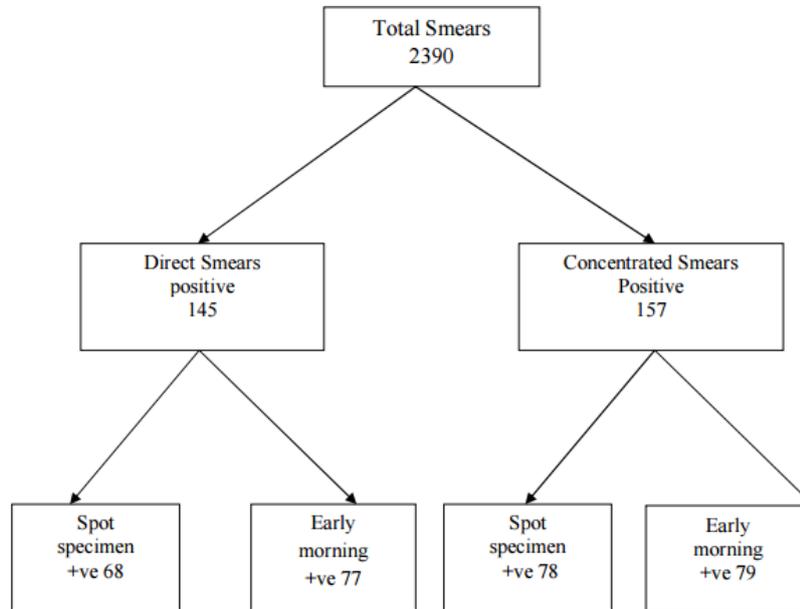
Segregation Of Male And Female Pulmonary Tuberculosis Cases:

As indicated by the Revised national tuberculosis control program a man is characterized as an instance of pneumonic tuberculosis regardless of whether one of the 2 smears is sure for acid fast bacilli.

		Male	Female
Total		407	193
Tuberculosis cases	Direct smear positive	59	18
Tuberculosis cases	Concentrated smear positive	60	19

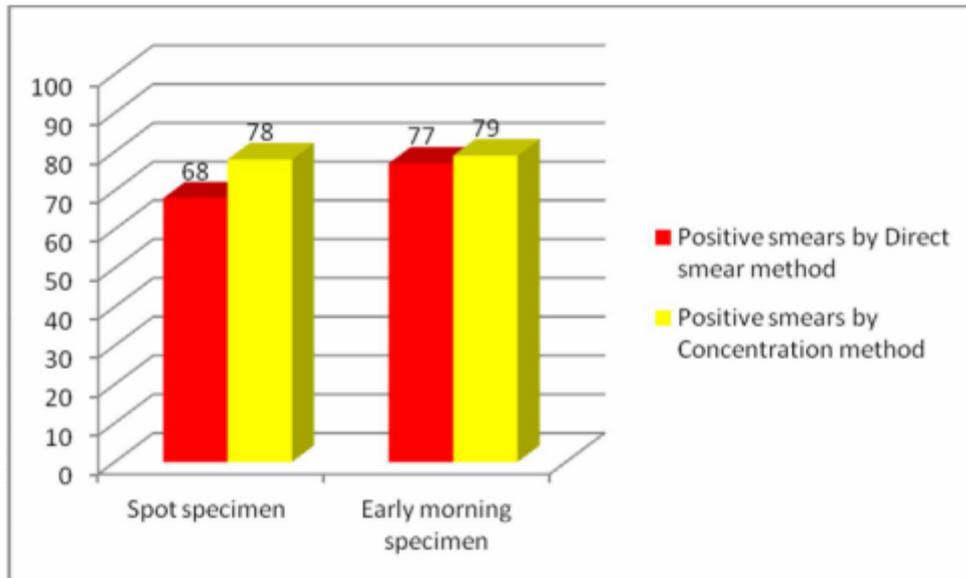
Revised national tuberculosis control program expects 5-15% of sputum positive patients among pulmonary tuberculosis suspects. In our investigation the level of cases among the pneumonic tuberculosis suspects is 13% which is well inside the RNTCP's desire.

Distribution Of Positive Smears By Direct And Concentrated Method On Day 1 And Day 2 Explained With The Help Of A Flow Chart:



From the above stream diagram we can reason that terribly there isn't much distinction between the early morning direct smear and spot concentrated smear.

Comparison Of Concentrated And Direct AFB Smears:



Bar diagram (5). The above bar diagram compares the results of direct and concentrated AFB smears on Day1 & Day 2. Here the number of direct smears positive on spot & early morning is 68 & 77 respectively. The number of concentrated smears positive on spot & early morning is 78 & 79 respectively.

Increase In The Yield Of Positive Smears By Concentration Technique:

Total number of smears read = 2390

Proportion of smears positive by concentrated method $157 / 2390 * 100 = 6.6\%$

Proportion of smears positive by direct smear method $145 / 2390 * 100 = 6.0\%$

Increase in the yield is calculated as the Proportion of smears positive by concentrated method minus the Proportion of smears positive by direct smear method, which is only 0.6.

Increase In The Yield Of Additional Number Of Pulmonary Tuberculosis Cases By Concentration Technique:

Total number of cases identified by concentrating spot as well as early morning sputum specimen is 79.

Total number of cases identified by a single concentrated spot sputum specimen is 78.

Total number of cases identified by direct smear method done by RNTCP protocol is 77.

Yield Of Concentrated AFB Smear In HIV Positive

There were absolutely 14 HIV positive patients .Among them 5 were sputum positive pneumonic tuberculosis cases. Among then 1 persistent was determined to have the assistance of concentration method alone. In HIV positive patients, the extent of positive smears by fixation technique short the extent of positive smears by direct 40 strategy (incremental yield) is equivalent to 20%. Be that as it may, the expanded yield isn't factually noteworthy.

Agreement Between The Concentration And The Direct Smear Method:

Concentrated smear results	Direct smear results		
	Positive	Negative	Total
Positive	67	10	77
Negative	0	518	518
Total	67	528	595

Kappa statistics = 92% (the agreement between the two methods is very good) (Tab.9) kappa co-efficient was calculated to know the agreement between spot concentrated and spot direct smear method.

Tab (10).Kappa insights = 99%, (the agreement between the two strategies is great) In (tab 10), kappa co-efficient was figured to know the understanding between early morning concentrated and early morning direct smear strategy. Kappa co-efficient is figured to know the agreement between 2 subjective information. When it is over 80% the understanding between the 2 information is great. From the over 2 tables the agreement between the spread technique and the concentrated strategy is settled.

IV. Discussion:

Affirmed conclusion of pulmonary tuberculosis must be set up by secluding Mycobacterium tuberculosis complex or discovering particular successions of DNA in respiratory specimens.⁸ Since culture and atomic tests are intricate and exorbitant, they are not broadly utilized in asset poor settings. In this situation smear microscopy remains the foundation of case discovery. So systems to enhance the affectability of smear microscopy and revelation of new straightforward calculation is basic.

Scrutinizing the outcomes, unmistakably a solitary spot concentrated AFB smear is comparable to 2 smears done by coordinate smear system. While there is contrast among spot and early morning direct smear, there is no real distinction among direct and early morning concentrated smear outcomes. There is no extra advantage in concentrating early morning examples as the expansion in the yield is measurably not noteworthy. The aggregate increment in the yield of concentrated strategy when contrasted with RNTCP technique is 0.6%.While the expansion in the yield is lower than different investigations, where the normal increment is 7%, this can be clarified. Our own is a tertiary consideration focus where the general population approach is just at a propelled arrangement , at this point the bacterial load would be sufficiently adequate to be sure by coordinate smear microscopy.

Fixation would be a financially savvy methodology considering the quantity of slides performed in RNTCP, lab outstanding task at hand , number of patient visits when all these are contemplated. By lessening the quantity of smears patient could be moved from seclusion before and treatment started early so the expense of hospital stay would be diminished. The concentration technique utilized in the examination utilizes ammonia which can be economically acquired and is additionally a decent fixative.⁷ The time required to peruse the smear gets lessened. There it is 7+/- 2,while in coordinate smear technique it is 10+/- 3 min.⁷ Despite the fact that the outcomes displayed here are engaging these are in the lab conditions, how the test performs in the field conditions must be seen.⁸ Regions in which encourage assessment is required are the requirement for follow up examinations of people found to have single spot concentrated AFB smear negative , to decide the ideal inspecting system to enhance sensitivity, the execution of single example approach in HIV constructive persons.⁸

Confinements of the investigation: Culture was not done by virtue of cost limitations. So we were not ready to decide sensitivity, rather we computed incremental yield. Another restriction is the intrinsic predisposition of the lab professional.

V. Conclusion

A properly prepared single concentrated spot AFB smear is as good as 2 direct AFB smear done by RNTCP method. The overall level of agreement between direct and concentration method is above 95%. Single concentrated smear results in less number of patient visits to the hospital so the number of dropouts during the diagnostic pathway is considerably reduced. Also the workload of the lab personnel is reduced. Although the cost of concentration of the specimen has to be kept in mind, the indirect cost made by the patient visits for 3 days till he collects the results are considered a single spot concentrated smear can be considered much more economical. The validity of concentration method under field conditions should be studied.

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