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Original Research Article

Role of induced sputum with hypertonic saline in the early diagnosis of no / inadequate sputum or sputum smear negative suspected cases of pulmonary tuberculosis

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ABSTRACT

Background: Pulmonary Tuberculosis is one of the common infections in the world, especially in developing countries like India and is a leading cause of morbidity and mortality worldwide. Therefore, early diagnosis and microbiological confirmation of pulmonary TB is important. This study was done to assess the role of induced sputum with hypertonic saline in suspected pulmonary TB patients who produce no or inadequate sputum or who are sputum for AFB smear negative.
Methods: 100 patients with clinical and radiological evidence of pulmonary TB with no or inadequate sputum or who are smear negative with spontaneous sputum were included in the study. Sputum was induced with 5ml of 3% hypertonic saline delivered through nebulizer and then was sent for Ziehl Neelsen staining examination.
Results: 96 patients could produce adequate sputum after sputum induction. In 47 patients, sputum for AFB smear was found positive after induction.
Conclusions: Sputum induction is a safe, cheap and non-invasive procedure and offers an alternative or additional approach in the diagnosis of sputum smear-negative suspected pulmonary tuberculosis patients and would enhance sensitivity for the diagnosis of tuberculosis.

Keywords: Hypertonic saline, Induced sputum, Sputum smear negative pulmonary tuberculosis (SSN-PTB)

INTRODUCTION

Pulmonary tuberculosis (PTB) is one of the leading cause of morbidity and mortality worldwide and in India. According to the recent estimates, the world had an estimated 10.4 million new TB cases as per the WHO estimates 2016. Over half of these were among men (5.9 million), and women constituted over a third (3.5 million). Ten percent of cases were among children. India had an estimated 2.84 million new cases of TB.[1] India has more new TB cases annually than any other country.[2] Direct sputum smear examination is being used as a basic diagnostic tool in the diagnosis of pulmonary TB.[3] The WHO also recommends the detection of acid-fast bacilli (AFB) in respiratory specimens as the initial approach to the diagnosis of pulmonary TB.[4] Though AFB smear is the most rapid, highly specific (98-99%) and low cost test but has poor sensitivity (30-70%).[5,6] Early diagnosis to reduce the period of infectivity is considered to be one of the most effective TB control strategies. Mycobacterial cultures are more sensitive than AFB smears (80-85%) but cultures require 3-8 weeks.[7,8] Sputum smear and culture examination still remain the gold standard in the diagnosis of pulmonary TB. But about 30% of new cases

of pulmonary TB may remain smear negative for AFB. Difficulties arise when a patient who is suspected of active pulmonary TB, both clinically and radiologically, does not produce sputum particularly in HIV positive, miliary Tuberculosis or NTM disease situations. If these patients are left untreated then about 70% of them may develop active TB in next 12 months.[9]

The various diagnostic methods which can help in early diagnosis of suspected SSN-PTB cases are listed in Table 1.

Table 1: Diagnostic methods in suspected SSN-PTB.

Sputum induction with hypertonic saline
Transtracheal needle aspiration
Radiologically guided transthoracic needle aspiration
Gastric lavage
Bronchoscopic procedures – Bronchial aspirate / BAL
Post Bronchoscopy sputum

Gastric lavage and fiberoptic bronchoscopy(FOB) have been regarded as the useful diagnostic procedures in persons with paucibacillary TB.[10] However, these methods are relatively invasive and not always accessible in TB-endemic settings.

Sputum induction is a safe procedure with a good diagnostic yield.[11,12] Sputum induction using 3% hypertonic saline has also been very well studied in the diagnosis of SSN-PTB. The various studies in this regard has reported the diagnostic yield varying from 35 to 95%.[13,14] In areas where FOB is not readily available or in resource-limited countries where FOB in every case of SSN-PTB is not feasible, sputum induction with hypertonic saline offers an alternative cheaper approach for diagnosing such cases.[15]

With this aim, the present study was done to assess the usefulness of sputum induction in establishing the diagnosis in patients with suspected pulmonary TB, who are unable to produce adequate sputum or are found negative on routine smear examinations.

METHODS

100 patients aged 18 yrs. and above with clinical and radiological features suggestive of pulmonary TB who visited the chest OPD or admitted in the TB and Respiratory Medicine ward at Geetanjali Hospital, Udaipur and also patients who visited Luhadia's Chest Clinic, Udaipur with either no sputum or inadequate sputum (only saliva or sputum quantity < 2 ml) or whose initial two sputum smear examinations for AFB were negative, were included in the study. Patient having frank Hemoptysis, respiratory distress, pneumothorax, hypotension, Spo2 <90%, unstable angina or arrhythmias and with poor general condition were excluded. The patients who had taken anti-TB treatment previously or patients who were already on anti-tuberculous therapy were excluded from the study.

Protocol for sputum induction

Sputum induction was performed on all patients selected by the above-mentioned criteria after a verbal informed consent

- A brief description of the procedure was given to each patient,
- The procedure was carried out in a well-ventilated room with windows open,
- To avoid contamination, the patients were asked to rinse and do gargles with water to clear debris from the mouth,
- The reservoir device of the nebulizer was filled with 5ml of 3% hypertonic saline solution,
- All patients were asked to inhale a mist of 3% hypertonic saline solution through mouth through the nebulizer,
- Inhalation was continued until an adequate amount of sputum sample (minimum 2 ml) was obtained or for a maximum period of 15 minutes or the patients complained of shortness of breath or wheezing,
- The inhalation was interrupted every 5 minutes so that the patient could expectorate sputum in a labelled sterile container.

The induced sputum samples were examined for AFB by Z-N staining in the laboratory as per RNTCP guidelines.

RESULTS

Out of 100 patients undergoing sputum induction, 70 were males and 30 were females. Out of these, 68% patients were having adequate sputum but were negative for AFB smear and 32% patients had cough with no / inadequate sputum. Sputum induction was successful in 96% of patients who could produce adequate volume (> 2 ml). 2 males and 2 female patients having dry cough were unable to produce sputum even after induction. Overall, 47% of patients were found positive on smear examination after sputum induction.

34 patients out of 68 (50%), who were having sputum and were negative on routine smear examination, were found positive on induced sputum smear examination. Sputum induction was successful in confirmation of diagnosis in 40.62% (13/32) of patients who were having cough with no/inadequate sputum (Table 2).

Table 2: Results of induced sputum for AFB smear.

Induced smear	Smear negative	No/inadequate sputum	Total
Positive	34	13	47
Negative	34	19	53

All patients with smear positive induced sputum were started on anti-tubercular treatment (ATT) as per national control program. And the remaining negative patients were advised further investigations.

In all the patients the procedure was found very safe as there was no major adverse effect or complication during and after the procedure. Only 2 patients had mild bronchospasm which were easily managed by bronchodilator nebulisation.

DISCUSSION

Though the sputum smear examination is the most reliable and cheap tool for diagnosis of pulmonary TB, but it's sensitivity is quite low.[5,6] It's sensitivity is further lower if the patient is either not producing sputum or producing scanty sputum and these cases are usually reported as negative for AFB smear.

In RNTCP these patients are given symptomatic treatment for 10-14 days and then their sputum is reexamined for AFB smear, leading to delay in the diagnosis and increased chances of transmission of tuberculosis. In these kind of patients, the induced sputum examination or BAL examination may help in early diagnosis. Sputum induction has various advantages over other methods. It is safer, cheaper and can be done as a OPD procedure.[16]

In our study, sputum induction was successful in 96% of patients in obtaining adequate amount of sputum. 34/68 (50%) patients, who were previously smear negative with spontaneous sputum, were found positive. Thus, sputum induction not only improved the quantity of the sputum but also improved the quality of the specimen.

The meta-analysis of sputum induction for diagnosis of PTB has shown that diagnostic yield in individual studies may range from 35-95%.[14] In our study the sputum induction has produced positive yield for tuberculosis in 47% patients which is matching with the range previously reported.[17-19]

CONCLUSION

Sputum induction offers an alternative or additional approach for microbiological confirmation of diagnosis of pulmonary TB in patients who produce no / inadequate sputum or who are sputum smear negative and would enhance sensitivity for the diagnosis of tuberculosis. It is a safer, cheaper, effective procedure and suitable for resource poor settings.

It also has very less contraindications and lesser risk of nosocomial infection as compared to BAL. Nevertheless, repeated sampling would increase the diagnostic accuracy and it should be incorporated in national program at least in selected group of patients.

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