

"Diagnostic Yield of Fibre Optic Bronchoscopy and CT Thorax in Patients Presenting With Hemoptysis and Normal Chest X-Ray".

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ABSTRACT OF THE SEED ARTICLE

The value of bronchoalveolar lavage in the diagnosisof sputum smear-negativepulmonary tuberculosis.

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Background and Objectives: Sputum smear staining for acid-fast bacilli is initial approach to the diagnosis of pulmonary tuberculosis (PTB) but more than 50% of cases are sputum smearnegative. This study was aimed to investigate the diagnostic value of fiberoptic bronchoscopy (FOB) guided bronchoalveolar lavage (BAL) in patients suspected to have tuberculosis.

Methods: This prospective cross-sectional study was carried out on 290 sputum smear-negative patients who were clinically suspicious for PTB in 2006-12. All patients were subjected to FOB andBAL,then BAL specimens stained and cultured.

Results: Of the 290 patients, 173 cases (59.7%) were men and 117 cases (40.3%) were women with the age of 52.6 ± 19.1 years (ranged 20-76 years). Of the total 290 BAL specimens, 110 specimens (38%) were positive for acid-fast bacilli. Sensitivity, specificity, PPV and NPV was 60%, 91%, 89% and 64%, respectively. Also, LR+ and LR- was 64.6% and 0.44%, respectively.

Conclusion: FOB guided BAL is a reliable, rapid and useful method for establishing the diagnosis of smear negative PTB with minimal complications.

SUMMARY

STUDY TITLE:

"Diagnostic yield of fibre opticbronchoscopy and ct thoraxin patients presenting with haemoptysis and normal chest x-ray" **AIM**:

- 1. To study the diagnostic yield of fibre optic bronchoscopy and ct thorax.
- Correlation ofct, fob and clinicalfindings in patients of hemoptysis with normal chest xray.

OBJECTIVES:

- 1. Clinical assessment of patient of hemoptysis with normal chest x-ray.
- 2. To study the role and diagnostic yield of fibre optic bronchoscopy in patients of hemoptysis with normal chest xray.
- 3. To study the role and diagnostic yield of ct thorax in patients of hemoptysis with normal chest xray.
- 4. Comparative study ofct ,fob and clinical findings in patients of hemoptysis with normal chest x-ray.

STUDY AREA:

All outdoor and indoor patient's 18 years and above attending department of respiratory medicine national institute of medicine science & research & hospital, jaipur, rajasthan

STUDY POPULATION:

Patients of haemoptysis with normal chest x-ray and of age 18 years and above .

INCLUSION CRITERIA:

- 1. Age 18 years and above.
- 2. One or more episodes of hemoptysis and normal chest X-ray.
- 3. Normal bleeding time, clotting time and prothrombin time.
- 4. Sputum for AFB smear-negative.
- 5. Willing to participate in the study and willing to give written informed consent.

EXCLUSION CRITERIA:

- 1. Severely dyspnoeic patients.
- 2. Unstable cardiovascular status.
- 3. Persistent massive hemoptysis.
- 4. Pregnant patients.



- 5. Patients with diagnosed disease with hemoptysis as its manifestation.
- 6. Immunosuppressed & HIV positive patients.
- 7. Patients with asthma and COPD.
- 8. Patients with bleeding diathesis and deranged coagulation profile.

SAMPLE TECHNIQUE AND SAMPLE SIZE

Sample size was calculated using the formula, $n = N/(1+Ne)^2$

Where: n is the desired sample size.

N is total population.

e is margin for error.

As per the Prevalence of hemoptysis in AMBER minimum sample size calculated by above formula is 221.

STUDY DESIGN:Observational and cross sectional

TIME FRAME: January 2019 to June 2022 STATISTICAL ANALYSIS:

The data collected will be analyzed for statistical validation with the software SPSS (Statistical Package for the Social Sciences).

I. INTRODUCTION

Coughing of blood emanating from the respiratory tract below the level of larynx is known as haemoptysis. Amount of blood varies from blood streaking of sputumto coughing up of massive volumes of pure blood which is life threatening . Bleeding can occur from any part of the lower respiratory tract. Bronchial artery being a high pressure system as compared to pulmonary system leads artery to massive hemoptysis.Hemoptysis of any degree needs thorough evaluation. The aim of evaluation is to find treatable cause and at times, to reassure the patient. The differential diagnosis of haemoptysis includes disorders arising within the airways and parenchyma^{2.} Inflammatory the pulmonary processes (e.g., bronchitis and bronchiectasis) and neoplasms are the most common causes of blood arising within the airways. Within the pulmonary parenchyma common causes are infections, such as tuberculosis, pneumonia, Aspergillosis or lung abscess. Pulmonary edema due to left atrial failure can also give rise to haemoptysis.. A chest radiograph (CXR) is THE INITIAL Diagnostic evaluation of haemoptysis. However, about 20-30% of patients with haemoptysis may show no obvious changes in the CXR.²

Fiber Optic Bronchoscopy (F.O.B) allows examination of airways and sampling of secretions from the proximal endobronchial tree⁶. However, F.O.B has limitations as it is not useful in detecting lesions within the distal airways and the lung parenchyma. CT- Scan of thorax is helpful in detecting both endobronchial and parenchymal abnormalities but it does not allow microbial and histologic diagnosis⁷

RESEARCH QUESTION:

Whether F.O.B and CT thorax are helpful in reaching a diagnosis in cases of hemoptysis with normal chest x-ray.

HYPOTHESIS:

FOB AND CT thorax may or may not be useful in reaching to a diagnosis in patients of hemoptysis with normal chest x-ray

AIMS & OBJECTIVES

AIMS

- 1. To evaluate the diagnostic yield of FOB AND CT Thorax in patients of hemoptysis with normal chest x-ray
- 2. To correlate the FOB, CT thorax and clinical findings in patients of hemoptysis with normal chest x-ray.

OBJECTIVES

- 1. Clinical assessment of patient of hemoptysis with normal chest x-ray.
- 2. To study the role and diagnostic yield of fibre optic bronchoscopy in patients of hemoptysis with normal chest xray.
- 3. To study the role and diagnostic yield of ct thorax in patients of hemoptysis with normal chest xray.
- 4. Comparative study of ct , fob and clinical findings in patients of hemoptysis with normal chest x-ray.

II. MATERIALS AND METHODS

STUDY DESIGN:Observational and cross sectional

STUDY AREA: All outdoor & indoor patients of age 18 years and above attending the Department of Respiratory Medicine of National Medical Science & Research, Jaipur Rajasthan presenting with hemoptysis with normal chest xray.

STUDY PERIOD:18 months **SAMPLE SIZE**: 221 patients.

TIME FRAME: July 2020 to June 2022

SELECTION CRITERIA OF PATIENTS

Inclusion criteria:

- 1. Age 18 years and above
- 2. One or more episodes of hemoptysis and normal chest X-ray.
- 3. Normal bleeding time, clotting time and prothrombin time



- 4. Sputum for AFB smear– negative.
- 5. Willing to participate in the study and willing to give written informed consent.

Exclusion criteria:

- 1. Severelydyspnoeic patients.
- 2. Unstable cardiovascular status.
- 3.Persistent massive hemoptysis
- 4. Pregnancy.

5.Patients with diagnosed disease with hemoptysis as its manifestation

- 6. Uncooperative patients.
- 7. Immunosuppressed & HIV positive patients.
- 8.Patients with asthma and copd.

III. METHODOLOGY

All the study subjects will be further reassessed for detailed clinical history, full clinical examination and laboratory investigations as per performa enclosed.

Patients of Hemoptysis with normal chest xray would be further evaluated by CT thorax and FOB to reach to a particular diagnosis.

Technique of FOB:

Prior to the procedure informed consent will be taken after excluding the patients with contraindication to bronchoscopy .patient will be kept nill per orally for 4 to 6 hours prior to the procedure nebulization will be done with 2%xylocaine via nebulizer under all aseptic precautions and strict supervision bronchoscopy will be done under local anesthesia via fibre optic bronchoscope. After inspecting the bronchial tree bronchial lavage will be done with 20 ml of normal saline and sample will be sent for examination and if required histopathological samples will be taken and sent for examination. After the procedure patient will be kept under observation and will also for pneumothorax, haemorrhage be observed infection and cardiac arrhythmias for 24 to 48 hours, proper disinfection of bronchoscope in between will be mandatory.

FOB-fibre optic bronchoscopy

BL-bronchial lavage

Technique of CT Thorax:

Non contrast CT thorax both mediastinal and lung window.

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CASE	PERFORM	Α			
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1) Nar	ne.				
$2) \Delta \sigma$	e/Sex				
(2) Rel	igion:				
A Occ	runation.				
5) Res	idence.				
6) Chi	ef complaints	& duration:			
7) Sm	oking status.	Evne			
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	Si	moking Index	monor		
8) H/C) present illne	e e			
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10)1 a	inny 11/0.				
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Oeden	na	Lymph	adenopathy		
Weigh	nt H	leight		Waist circumference	
BMI					
Respi	ratory exami	nation:-			
Other	Systems:				
CVS:-					
CNS:-					
GIT:-					
Invest	tigations:-				
1. C	XR (PA view))			
2. C	T THORAX				
3. C	OMPLETE B	LOOD PICTUR	Е		
a) H	B%:-				
b) T	LC:-				
c) D	LC:- POLYM	IORPHS-	LEUCOCYTE-	MONOCYTE-	
d) E	SR				
4. R	ANDOM BLO	OOD SUGAR- I	HIV status		
5. L	IVER FUNCT	FION TEST-			
a) T	OTAL BILIR	UBIN:-			
b) So	GOT:-				
c) S(GPT:-				
d) A	LKALINE PH	HOSPHATASE			
6. R	ENAL FUNC	TION TEST:-			
a) B	LOOD UREA				
b) SI	ERUM CREA	TININE			
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8. E	CG				
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Participant Informed Consent Form(English)			
Protocol/Studynumber:			
Participant identification number for this trial:			
Title of Project:	Name	of	the
Principal Investigator:			
Tel. No. (s)			

The contents of the information sheet dated that was provided have been read carefully by me/ explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks/ benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from NIMS. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

------ (Signatures /Left Thumb Impression) Date :

Place :

 Name of the Participant:
 Son/Daughter/Spouse of:

 Complete
 postal
 address:

This is to certify that the above consent has been obtained in my presence.

the Principal Investigator)Date: Place:

1) Witness 2) Witness

------ Signatures

(Signatures of



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सहभागी सुचित सहमति प्रपत्र

इस जांच के लिए सहभागी पहचान नम्बर		
अनुसन्धान		
ร์โน้ซ		
मुख्य अन्वेषक का नाम	फोन नंबरः	
मैंने दिनांक के सूचना पत्र	में दिये गए सभी तथ्यो का	पड़ लिया हैं। मुझे समझ
आने वाली भाषा मैं विस्तारपूर्वक बता दिया हैं अं करता हूँ कि मुझे प्रशन पुछने का अवसर दिया ग	ोर मैनें तथ्यो को भली भांति ग हैं।	ा समझ लिया हैं। मैं पुष्टि
मुझे अध्ययन की प्रकृति, उद्देश्य और इसके सम्भा	वित लाभ/जोखिमों और अध	व्ययन की सम्भावित अवधि
अन्य प्रासंगिक जानकारी के बारे में विस्तार पूर्वक	समझा दिया गया है। मैं स	मझता हूँ कि इस अध्ययन
में मेरी भागिधारी स्वेछिक हैं और इस अध्ययन सं	ो किसी भी समय बिना कोई	र् कारण बताए, बिना मेरी
चिकित्सा देखभाल या कानूनी अधिकारों के प्रमावित	हुए अपना नाम वापिस ले	सकता/सकती हूँ।
मैं समझता हूँ कि इस अनुसन्धान में मेरी सहभा	गिता से मेरे बारे में एकत्र	जानकारी और चिकित्सीय
नोटों को निम्स अस्पताल के जिम्मेदार लोगों द्वारा	देखा जायेगा। मैं इन व्यक्ति	यों को अपने रिकार्ड देखने
कि अनुमति प्रदान करता∕करती हूँ।		
मैं उपर्युक्त अध्ययन में भाग लेने के लिए अपनी स	हमति प्रदान करता/करती हॅ	ţı
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पेता∕पति का नाम		
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वह प्रमाणित किया जाता है कि उपर्युक्त सहमति मे	री उपस्थिति में ली गई हैं।	
रुख्य अन्वेषक के हस्ताक्षर	दिनांक	स्थान
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सकी तीन प्रतिलिपीयाँ बनाईये- (1) मरीज (2)	अनवेश्क (3) इन्सटिर	व्यश्नल ऐचीकल कमेरी



Participant Information Sheet (PIS)

- 1. What is the background to and purpose of the study?
- To find out the diagnostic yield of bronchoalveolar fluid in clinicoradiologically suspected sputum smear negative cases of pulmonary tuberculosis
- 2. Do I have to take part?
- Yes, for history taking, physical examination & investigations.
- 3. What will happen to me if I take part?
- You will be examined medically & investigated.
- 4. What do I have to do?
- Take part in your examination & investigations.
- 5. What are the possible side effects, risks and discomforts of taking part?
- Some of the known side effects associated with fibre optic bronchoscopy include bleeding,infection,myocardial infarction,pneumothorax,haemorrhage,cardiac

arrhythmia and lung collapse if airway is injured during the procedure.

6. What are the possible benefits of taking part? Health check-up / Diagnosis of Diseases.

7. What if new information becomes available? It will be published as Scientific Research.

8. What are the costs of taking part?

NIL.

9. How will my personal data be used?

- Only for Scientific Publications.
- 10. Will there be provision for free treatment for research related injury?
- NO.
- 11. Will compensation be paid to the subjects if disability or death results from such injury?
- NO.
- 12. Whom should I contact if I need more information or help?
- Dr.P. R. GUPTA (9414071748)
- Dr. KUNAL VAGHELA (9106430444)