

# THE INTERNATIONAL JOURNAL OF SCIENCE & TECHNOLEDGE

## A Comparative Analysis of Suggestive Radiology versus Sputum Test in the Diagnosis of Tuberculosis at the Defence Forces Memorial Hospital, Kenya

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### **Abstract:**

*Background: Worldwide, there is an increase the number of TB cases in the developing world where the HIV/AIDS scourge has seen resurgence in the numbers of TB cases. The tendency to use a combination of radiological investigations along with sputum studies for TB in Kenya without due regard to the radiation exposure and additional cost warrants a comparative evaluation of the efficacy of the diagnostic tests with a view of avoiding unnecessary tests.*

*Goal of the Study: The purpose of the study was to determine the effectiveness of radiology imaging versus sputum test in the diagnosis of tuberculosis at DFMH.*

*Methods: A retrospective comparative analysis of hospital records for TB patients with a view of determining the relationship between suggestive radiology findings for TB versus results of sputum bacteriological studies in the diagnosis of TB at the Defence Forces Memorial Hospital (DFMH) between January and July 2014. The researchers extracted the sputum results, clinical diagnosis, suggestive radiology findings for Tuberculosis, and patient's demographic variables from the hospital data treatments records using a checklist at the Comprehensive Care Clinic (CCC). Data was then summarized and presented in form of tables, bar graphs and pie charts.*

*Results: Data from the 50 study subjects' records revealed that the majority were of male gender at 72%, while the rest was the female gender at 28%. The mean age of the patients was 34.16 years with a range of between 17-48 years. The majority (58.0%) of the patients' diagnosis indicated suggestive for TB by use of X-ray whereas 14.0% of the patients had normal findings. TB diagnosis made by CT scan was 24% of the patients. Approximately 56.0% of the patients showed negative sputum results while 44.0% results showed the test was positive (p-value of 0.045). Out of the 29 suggestive cases by X-ray, 42.1% had a negative lab test while 57.8% had a positive sputum lab test. Whereas chest x-ray showed that some patients' exams were normal, majority (85.7%) of those cases were reported as positive for TB by lab test and only 14.3% were reported as negative for TB by lab test.*

### *Conclusions and Recommendations*

*The use of sputum tests for detection of pulmonary TB is much more sensitive than suggestive radiological findings as previously expressed by other scholars. The role of radiology could be limited to the extra-pulmonary TB diagnosis or situations in which patients lack sputum.*

### *Recommendation*

*A review of the TB management protocols with a view of limiting concurrent use of radiological and a laboratory investigation for pulmonary TB could scale down the cost of TB investigations.*

**Keywords:** Suggestive Radiology versus sputum test for TB

### **1. Background of the Study**

Tuberculosis (TB) is a common and often fatal chronic infectious disease caused by various strains of mycobacterium especially Mycobacterium tuberculosis that mainly affects the lungs. Despite affecting mainly the lungs, TB is a multi-systemic disease that affects almost all body tissues except the hair, teeth, and the nails. When TB affects other parts of the body, the term extra-pulmonary TB is applied (EPTB). Extra-pulmonary TB infections include tuberculous pleurisy, tuberculous meningitis, scrofula of the neck, urogenital tuberculosis, and Pott's disease of the spine, just but to mention a few.

According to the WHO Fact Sheet of 2014, tuberculosis (TB) is second only to HIV/AIDS as the greatest killer worldwide due to a single infectious agent. In the WHO statistics, 8.6 million people fell ill with TB and 1.3 million died from TB in the year 2012 alone. The report further noted that over 95% of TB deaths occur in low-income and middle-income countries, and it is among the top three causes of death for women aged 15 to 44. According to WHO (2012), it was reported that among the 22 leading countries with TB

globally, Kenya was ranked 10<sup>th</sup>. In Kenya, of the notified 99,159 TB cases put on treatment, 37% were new smear positive, 29% were PTB, 10% were retreatment cases and the rest were EPTB (Division of Leprosy Tuberculosis and Lung Disease, 2012).

The gold standard diagnostic test for TB is finding *Mycobacterium tuberculosis* bacteria in a clinical specimen taken from the patient. A complete medical evaluation for tuberculosis (TB) must include a medical history, a physical examination, a chest X-ray (CXR) and microbiological examination (of sputum or some other appropriate sample). It may also include a tuberculin skin test, other scans and X-rays, surgical biopsy.

This study therefore will endeavor to determine the effectiveness of radiological imaging versus sputum test in the diagnosis of tuberculosis at the Defence Forces Memorial Hospital.

### *1.1. Statement of the Problem*

TB is a national disaster of major public health concern. There have been increasing cases of multi-drug resistance TB despite the many strategies in place to prevent the spread and occurrence of new cases. The use of laboratory diagnosis for PTB is considered a gold test to detect the presence of *M. tuberculosis* in highly suspected patients. However, the establishment of a definite/confirmed diagnosis of PTB may require invasive and expensive serological/radiological investigations (Arora and Gupta, 2006). In addition, prompt and accurate diagnoses of PTB are the key elements for an effective treatment (Rockwood, 2007), but they are often delayed primarily due to the difficulty in isolating the small number of *Mycobacterium tuberculosis* present in the affected tissues (Fanning, 1999). Therefore, it is of high clinical importance to predetermine and detect the PTB lesions using non-invasive techniques (e.g. radiological exams) in highly suspected patients, in order to avoid unnecessary invasive and sophisticated/expensive procedures.

The purpose of this research is to establish the effectiveness of radiology imaging vs sputum test in the diagnosis of tuberculosis at Defence Forces Memorial Hospital, Nairobi County – Kenya.

### *1.2. Study Objectives*

#### 1.2.1. Broad Objective

To evaluate the effectiveness of radiological imaging versus sputum test in the diagnosis of PTB among adult clients undergoing Chest X-ray imaging procedures at the Defence Forces Memorial Hospital, Nairobi, Kenya.

#### 1.2.2. Specific Objectives

1. To determine the effectiveness of chest x-ray in the diagnosis of PTB at the Defence Forces Memorial Hospital.
2. Compare the diagnostic efficiency of chest radiographs and sputum bacteriological studies
3. Determine the socio-demographic characteristics of patients with PTB at the DFMH

## **2. Literature Review**

### *2.1. Introduction*

The World Health Organisation (WHO) in 1993 announced that tuberculosis (TB) was a ‘global emergency’ requiring significant investment in both programmatic and research sectors. Despite these warning to partner countries and global agencies, the TB burden is still significantly high with approximately 8.5 million people falling ill and a resultant effect of 1.3 million people dying from the disease in 2012 (WHO, 2012). The management of TB and especially treatment is often dependent on lengthy drug regimens that often lead to non-compliance in addition to diagnosis that still remains challenging more so in resource poor settings. According to WHO (2011), sputum smear microscopy and culture are established diagnostic standards, with chest X-ray (CXR) being called into question due to limited diagnostic accuracy and poor film quality, particularly in low-resource settings where infrastructure is often erratic and unreliable.

In 1882, the radiologic diagnosis of TB started after Roentgen's discovery of x-rays. Fluoroscopy was used in the early part of the 20<sup>th</sup> century to detect cavitory TB, because experienced fluoroscopists could easily detect cavities. Over the years, improvements in technology, coupled with extensive investigation into the radiologic patterns of pulmonary TB, have resulted in diagnostic imaging being an essential adjunct to the clinical and microbiologic diagnosis of this disease. These events contributed to the routine practice of documenting cavitory disease and following up the disease on film. Radiology provides essential information for the management and follow up of these patients and is extremely valuable for monitoring complications (Andreu et al., 2004).

### *2.2. Diagnostic Imaging in PTB*

The use of radiological imaging in the management of PTB has had a significant impact in the diagnosis of the disease. The radiological features show considerable variation, but in most cases they are characteristic enough to suggest the diagnosis. The spectrum of radiologic manifestations of PTB can pose a variety of diagnostic and management challenges. PTB infection often leaves long term sequelae of infection, particularly granulomatous nodules, cavitation, and fibrosis; distinguishing dormant disease from reactivation is not always clear-cut. Despite sputum smear microscopy being the established diagnostic standard and even as more sensitive molecular tests for pulmonary tuberculosis (PTB), such as GeneXpert, become available, CXR remains necessary in the evaluation of patients with compatible symptoms but negative laboratory results. A study on the radiologic manifestations of pulmonary tuberculosis found that chest film was the mainstay in the radiologic evaluation of suspected or proven pulmonary TB whereas CT was occasionally useful for clarifying confusing findings but had not been conclusively shown to have a significant

impact on patient management (McAdams, Erasmus and Winter, 1995). In CXR, PTB occurs as patchy irregular opacities centered usually on the upper lobe, cavities within such lesions, streaks of fibrosis radiating from the hilum, calcification and solitary rounded shadows. The author further explains that millitary TB is a blood borne dissemination of TB organisms with wide spread glaucomatous disease which presents as a pyrexia and weight loss with no localizing features. CXR presents as discrete 2mm shadows throughout both lungs usually without bilateral hilum adenopathy (Allan et al., 1997). As TB is mainly transmitted by sputum smear-positive patients, the DOTS strategy strongly promotes smear microscopy for the diagnosis of TB among symptomatic patients, the so-called TB suspects. According to Trebucq (2004), chest X-ray is restricted to diagnosing smear-negative TB among those suspects whose sputum examination is negative. Chest radiography, however, remains a key tool for the clinical diagnosis of pulmonary tuberculosis. Previous studies suggest that chest radiograph abnormalities in tuberculosis are not specific and levels of intra- and inter-reader agreement are very variable (Balabanova et al., 2005; Shaw, Hendry and Eden, 1990). Studies show that the use of CXR for the diagnosis of TB suspects would lead to about 37% over-diagnosis (Toman, 1979; 2004) whereas also if the use of CXR would be restricted to sputum negative suspects, the over-diagnosis would still be substantially high (van Cleeff et al., 2003). A cost-effective analysis study done on the role and performance of CXR in Nairobi concluded that the diagnostic pathway Ziehl-Neelsen (ZN) followed by CXR was more cost-effective as compared to CXR followed by ZN though when cost of treatment was also considered CXR followed by ZN became more cost-effective. The challenges in resource-poor settings may put the diagnosis of TB using smear microscopy to question (Van Cleeff et al., 2005). This is confirmed by a study by Mundy et al. in 2002 in a rural district in Malawi that showed smear-microscopy becoming less accurate when throughput was high and depended on the health and presence of key workers.

Although chest radiography is the mainstay in the evaluation of pulmonary TB, CT generally is required to detect fine lesions overlooked on chest radiographs, to define equivocal lesions, or to evaluate complications. Lee et al. (1996) concluded that CT can be helpful in the diagnosis of pulmonary tuberculosis in most cases. On the basis of CT findings, distinction of active from inactive disease can be made in most cases. High-resolution CT is useful in understanding the pathologic process of the disease and in determining disease activity in selected cases. This article describes the characteristic CT findings of various forms of pulmonary TB and non-tuberculous mycobacterial infection according to immune status of the patients, and assesses the role of CT in the diagnosis and management of pulmonary TB.

### **3. Methodology**

#### *3.1. Study Site*

The Defence Forces Memorial Hospital Nairobi, which serves about 2,000 military personnel plus their family members.

#### *3.2. Study Design*

The research design was a retrospective study in nature geared towards determining the relationship of radiological imaging versus sputum test in TB diagnosis.

#### *3.3. Study Population*

All hospital record of patients that received imaging services at DFMH with PTB as their diagnoses formed the study population in the study.

#### *3.4. Inclusion Criteria*

All patients who received imaging services at X-ray department at DFMH and sputum screen for PTB according to their clinical presentations.

#### *3.5. Sampling Criteria*

Purposive sampling selection of the study subjects from the target population.

#### *3.6. Data Collection Tool*

Observational checklist

#### *3.7. Data Storage*

Data entry into a computer database designed using MS-Access application. The data was cleaned and validated, after which the data was stored in both hard and soft copies and backed up in compact discs and removable disks.

#### *3.8. Data Analysis*

Data coding and analysis using the SPSS/PC+ Version 12.0 program to generate Descriptive statistics of the continuous and categorical variables at 0.05 level of significance ( $p=0.05$ ) and a 95% confidence interval.

3.9. Ethical Considerations

The researchers sought the approval of the study procedures by the departmental Scientific Steering Committees (SSC) of the College of Health Sciences (JKUAT) and the Medical and Administration Committee (MAC) of Defence Forces Memorial Hospital. Data entry in password-protected computers without links to identifiers was undertaken.

4. Results

4.1. Socio-Demographic Data

Data from a total of 50 study subjects was collected where majority was the male gender at 72% while the rest was the female gender at 28% as shown in figure 1. The mean age of the patients was 34.16 years with a range of between 17-48 years (Table 1).

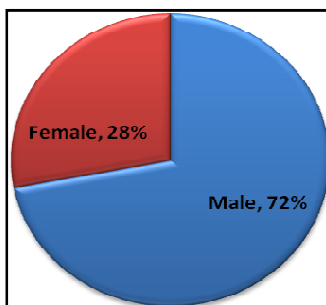


Figure 1: Distribution by gender

Mean	34.16
Median	31.00
Mode	30
Minimum	17
Maximum	48

Table 1: Age of the Patients

4.2. Radiological Exams

The findings of the study showed that majority (58.0%) of the patients’ diagnosis indicated suggestive by use of X-ray while those found to be negative 4.0% whereas 14.0% of the patients had normal readings as shown in table 2. Diagnosis made by CT scan was 24% of the patients.

	CT Positive	Chest X-ray			Total
		Negative	Normal	Suggestive	
Male	12	2	7	15	36
	33.4%	5.6%	19.4%	51.7%	
Female	0	0	0	14	14
	0.0%	0.0%	0.0%	48.3%	
Total	12	2	7	29	50
	24.0%	4.0%	14.0%	58.0%	

Table 2: Radiological Results (P-value 0.007)

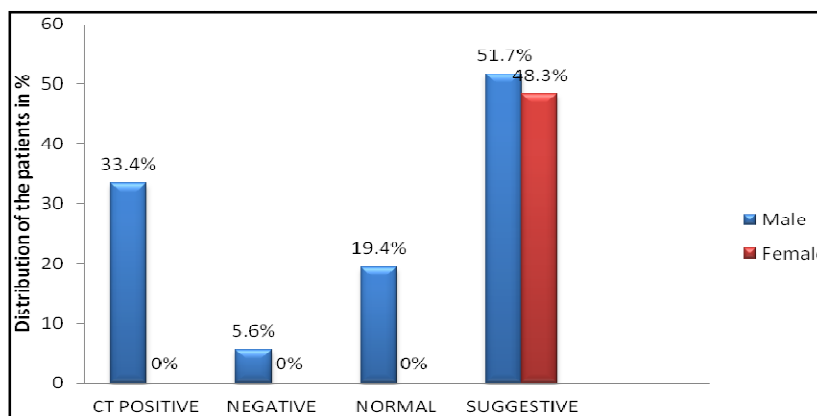


Figure 2: Radiological Results

4.3. Sputum Lab Test

The findings of the study indicate that approximately 56.0% of the patients showed negative sputum results while 44.0% results showed the test was positive at a p-value of 0.045 as shown in table 3.

	Lab test		Total
	Negative	Positive	
Male	17	19	36
	47.2%	52.8%	100.0%
Female	11	3	14
	78.6%	21.4%	100.0%
Total	28	22	50
	56.0%	44.0%	100.0%

Table 3: Lab Test Results  
P-value 0.045

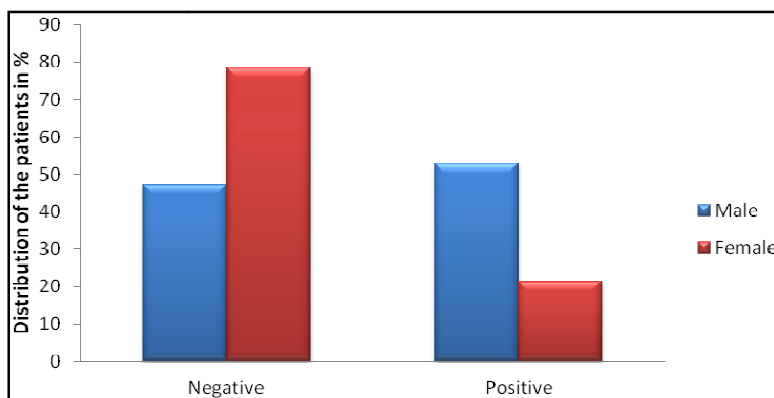


Figure 3: Lab Test Results

4.4. Radiological Exams versus Lab Test

Findings from the study showed that out of the 29 suggestive cases by X-ray, 42.1% had a negative lab test while 57.8% were positive by lab test. Whereas chest x-ray showed that some patients' exams were normal, majority (85.7%) of those cases were positive by lab test whereas only 14.3% were negative by lab test (Table 4).

Chest X-ray	Lab test		Total
	Negative	Positive	
Normal	1	6	7
	14.3%	85.7%	100.0%
Suggestive	15	14	29
	51.7%	48.3%	100.0%
Negative	0	2	2
	0.0%	100.0%	100.0%
Total	16	22	38
	42.1%	57.9%	100.0%

Table 4: Chest X-ray versus Lab Test

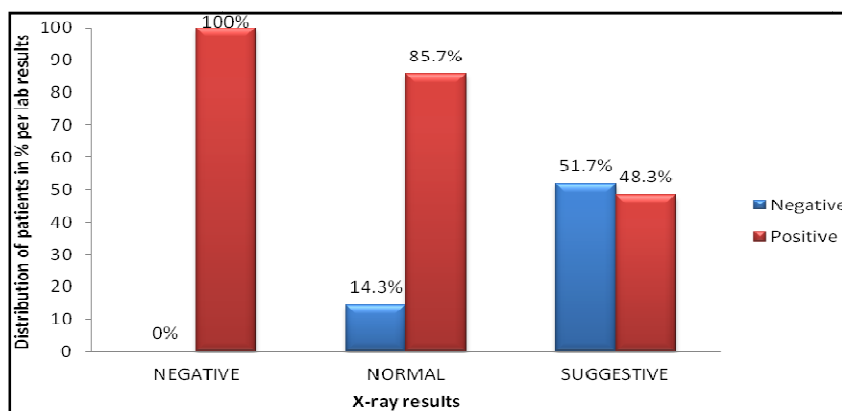


Figure 4: Radiological results versus lab test

Further, the findings showed that all cases 100% (12) reported positive by CT scan were negative by lab test (Table 4).

	Lab test		Total
	Negative	Positive	
CT Positive	12	0	12
	100.0%	0.0%	100.0%

Table 5: CT Scan versus Lab Test

#### 4.5. Type of TB

Results of the study showed that majority (76%) of the cases were of the pulmonary type of TB as reported by X-ray while 24% were of extra-pulmonary type of TB (figure 5).

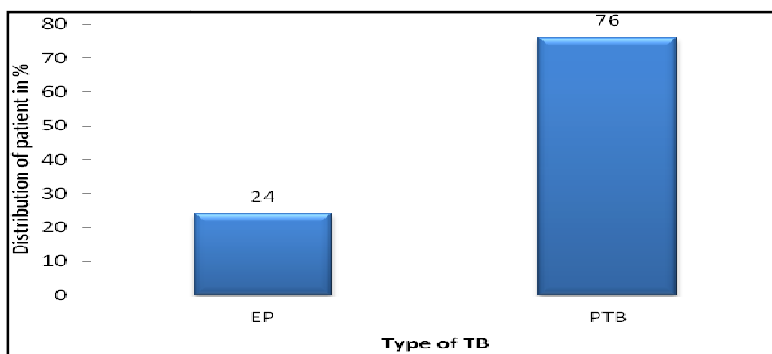


Figure 5: Type of TB

### 5. Discussion

#### 5.1. Socio-demographic Characteristics

Data from the 50 study subjects comprised mainly the male gender at 72%, while the rest was the female gender at 28%. According to Diwan and Thorson (1999), globally, the ratio of female to male tuberculosis cases notified is 1/1.5–2.1 and that 70% more smear-positive male than female tuberculosis patients are diagnosed every year and notified to the WHO. According to WHO (2008), on Gender and TB: pointers from routine records and reports, men accounted for a higher proportion of notified TB cases (63% or 64%). The mean age of the patients was 34.16 years with a range of between 17-48 years (table 1).

#### 5.2. Radiological Exams

The findings of the study showed that majority (58.0%) of the patients’ diagnosis indicated suggestive by use of X-ray while those found to be negative 4.0%, whereas 14.0% of the patients had normal readings as shown in table 2. Diagnosis made by CT scan was 24% of the patients.

#### 5.3. Sputum Lab Test

The findings of the study indicate that approximately 56.0% of the patients showed negative sputum results while 44.0% results showed that the test was positive at a p-value of 0.045. Comparatively the findings are somewhat similar with those of a study in China, where that showed that 92 patients (33%) were diagnosed as definitive TB, 112 patients (40%) were probable PTB, and 76 (27%) were non-TB (Fan *et al.*, 2014).

#### 5.4. Radiological Exams versus Lab Test

Findings from the study showed that out of the 29 suggestive cases by X-ray, 42.1% had a negative lab test while 57.8% were positive by lab test. The findings concur with those from Nairobi, Kenya by Van Cleeff *et al.* (2005) that concluded that depending whether CXR was performed on all suspects or on smear-negative suspects only, 22-45% of patients labeled as "TB" had a negative culture. Whereas chest x-ray showed that some patients' exams were normal, majority (85.7%) of those cases turned positive for TB by lab test whereas only 14.3% turned negative by lab test. This further agrees with a study by Pai (2013) in India in which it was concluded that culture was very useful in diagnosing smear-negative TB and drug-resistant TB.

Further, all cases 100% (12) reported positive by CT scan were negative by lab test, that was further supported by findings of a study by Lee *et al.* (1996), whereby 133 of 146 patients (91%) with TB without HIV/AIDS were correctly diagnosed as having pulmonary tuberculosis while 32 of 42 patients (76%) without tuberculosis were correctly excluded with CT. Other studies show that high resolution CT could predict the risk of PTB with good reproducibility and can select patients having a high probability of PTB (Nakanishi *et al.*, 2010) which could further be valuable in treatment decisions (Hatipoğlu *et al.*, 1996). Although chest radiography is the mainstay in the evaluation of pulmonary TB, CT generally is required to detect fine lesions overlooked on chest radiographs, to define equivocal lesions, or to evaluate complications.

#### 5.5. Conclusions and Recommendations

The use of sputum tests for detection of pulmonary TB is much more sensitive than suggestive radiological findings as previously expressed by other scholars. The role of radiology could be limited to the extra-pulmonary TB diagnosis or situations in which patients lack sputum.

#### 5.6. Recommendation

A review of the TB management protocols with a view of limiting concurrent use of radiological and a laboratory investigation for pulmonary TB could scale down the cost of TB investigations.

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