

**Original Article****Diagnosis of pulmonary tuberculosis under Directly Observed Sputum Collection “DOSC” in a general Sudanese hospital**

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**ABSTRACT**

**Background:** Tuberculosis is a major cause of illness and death worldwide, especially in Asia and Africa. The objective of this study was to compare the results of bacteriological examination of tuberculosis suspects taken under direct observation during collection with specimens taken without observation. **Methods:** This was analytic study to compare sputum results taken from TB suspects under direct observation during collection of the specimens by the laboratory technician, and those taken without observation. The study population was Pulmonary TB suspects attending Gedarif Teaching Hospital, Gedarif, Sudan. The sample size was calculated as 164 for the cases and 164 for the controls. The patients in the study group were observed by the laboratory technician while coughing to provide the sputum samples for testing AFB for pulmonary tuberculosis diagnosis. The sputum samples for the control group were taken without observation. A tested questionnaire was used to collect demographic data and the laboratory register was used to obtain sputum. Analysis was done by SPSS version 16. Informed consent was obtained from all participants. **Results:** 46.3% of the samples were positive when the sputum was collected under direct observation by the laboratory technician while 29.9% of the samples were positive when taken without observation. **Conclusion:** The sputum collection under direct observation by the laboratory technician to investigate pulmonary tuberculosis provided more positive results compared to specimens collected without observation.

**1. Introduction**

Tuberculosis is a major cause of illness and death worldwide, especially in Asia and Africa[1]. Estimates of the global burden of TB in 2009 were 9.4 million incident cases and 14 million prevalent cases. Death among TB and HIV co-infection was 380000. Most cases were in the South-East Asia, African and Western Pacific regions constituted 35%, 30% and 20%, respectively[2]. Sudan shoulders 11% of TB burden in the East Mediterranean Region and the disease is recognized as a major health problem in the country[3].

Smear positive pulmonary tuberculosis (PTB) cases are more infectious than the smear negative cases. The TB case detection rate remains very low in Sudan and in Gedarif State is not an exception; however there is an increase in smear-negative PTB which could be attributed to several factors including poor quality of sputum smear-microscopy. Microscopy remains the mainstay of rapid TB case detection in the country[4]. The sensitivity of the direct Ziehl-Neelsen smear depends on the

diligence of the laboratory technician, the way of sputum collection and the use of appropriate technique[5].

All Tuberculosis Basic Management Units “TBMUs” in Gedarif state have laboratory facilities since the sputum testing is a corner stone in TB diagnosis, but the program suffers a high prevalence of smear negative results.

Among the 25,024 Tuberculosis patients diagnosed in the country in 2006, 8746 (35%) were smear negative[6]. It was observed that, some patients do not cough from the lung-bronchial tree when asked to provide sputum for testing acid fast bacilli. If this assumption is true, it may answer the question why Sudanese tuberculosis patients have a high prevalence of smear negative results of pulmonary tuberculosis which leads to low case detection rate of the disease. This could be attributed to the fact that when the patient does not cough from the lung bronchial tree, and provides saliva from the upper respiratory tract, a negative result may be obtained which increases the misdiagnosis of the disease.

These patients may continue transmission of infection, which adds to the TB burden in the community[7].

The objective of the current study was to compare the results of bacteriological examination of tuberculosis suspects taken under direct observation by the laboratory technician, with specimens taken without observation.

## 2. Research methods

This was an analytic study to compare sputum results taken from TB suspects under direct observation during collection of the specimens with specimens taken without observation.

TB suspect attending Gedarif Hospital TBMU were sent to the medical laboratory for sputum testing to detect acid fast bacilli "AFB". Those TB suspects were registered and assigned randomly either in the study or the control group by random allocation. Matching for age and gender were done. (TB suspects were defined as individuals who had cough of  $\geq 2$  weeks).

The sample size was taken as 164 for the cases and 164 for the controls. Two laboratory technicians were involved in the study after having a refreshing training for two days in how to collect and investigate sputum for AFB. Ziehl-Neelsen was under internal control with each batch and the laboratory is under external quality assurance system. All cough-inducing procedures were performed in a room that meets the ventilation requirements[8].

The subjects in the study group were observed while coughing to produce a specimen to be tested for AFB. They were asked to cough to bring 5-10 ml of sputum (From the Lung-bronchial tree with minimal amount of upper respiratory tract secretion). The technician confirms that the secretion is thick in consistency and yellowish in color. If the specimen was watery fluid/ colorless the subject was asked to try another sample. All the samples were obtained spontaneously, so no induction was

used. Before coughing and obtaining the sample, the subject was asked to rinse the mouth, clear the nose and throat, try a hot drink, place both hands in the waist, take 2-3 deep breaths and cough up vigorously so the sputum comes out from the lungs[9]. Measures were taken to avoid contamination of the outside of the tube. All subjects provided two samples, one at the time of arrival at the laboratory and the other was an early morning specimen taken in the laboratory to assure proper collection. The laboratory technicians were keeping a distance from TB suspects while they were coughing as well as the room was well ventilated to reduce transmission of the mycobacteria[10]. All specimens obtained were investigated for the presence of acid fast bacilli "AFB".

The collection of the sputum for the control group was done as a routine without interference from the laboratory technician. A pre tested questionnaire was used as a tool for data obtained from the study and control groups. The SPSS for Windows software version 16(SPSS, Chicago, Illinois, USA) was employed to analyze the data. Descriptive statistics were used. Comparisons between groups were made using the persons' Chi-squared to test significance and a  $P < 0.05$  was considered significant.

An ethical approval was obtained from the ethical committee, Ministry of Health in Gedarif state. A written consent was obtained from the cases and the controls. Confidentiality of the data was realized. Respect and dignity was in place during the study. The right of the subjects to withdraw from the study at any time without affecting their right to receive the needed care was explained to the participants.

## 3. Results

The smear positive pulmonary TB was 46.3% when the sputum was collected under direct observation by the laboratory technician while it was 29.9% when collected without observation.

**Table 1:** Results of sputum examination when collected under direct observation compared to routine collection

Groups	Sputum results		Total	p
	Positive	Negative		
Study	76 (46.3%)	88 (53.7%)	164	<b>0.017</b>
Control	49(29.9%)	115(70.1%)	164	
Total	125(38.1%)	203(61.9%)	328	

## 4. Discussion

The results showed that a high proportion of TB suspects were sputum positive for both cases and controls. Sputum positivity for AFB varies considerably from one location to another[11].

The findings of the current study were higher than results from South Africa where smear positivity was 18% among TB suspects and 25.58% from India among TB/HIV co-infected patients[12,13].

However these findings were lower than the findings reported in northern Tanzania in a TB/HIV endemic setting and Mumbai in India[14,15].

According to our findings, the high prevalence may be due to the fact that the medical doctors and the medical assistants don't send the TB suspects to the laboratory for sputum testing unless they are sure that the results will be positive. In this respect

## 5. Conclusion

The sputum collection under direct observation by the laboratory technician to investigate pulmonary tuberculosis provided more positive results compared to specimens collected without observation.

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many patients may be misdiagnosed. The presence of mycobacterium tuberculosis in the sputum samples in this study was much higher (46.3%) when the sputum sample was collected under direct observation than when the sample was collected without observation (29.9%), and the relation was significant ( $p=0.017$ ).

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