ISSN: 1813-1638

The Medical Journal of Tikrit University

Available online at: www.mjotu.com

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Keywords:

TB,
GenecXpert text ,
Direct sputum smear

ARTICLE INFO

Article history:

Received 30 Jun 2021
Accepted 13 Jul 2021
Available online 5 Dec 2021

Comparism between GeneXpert test and direct sputum smear in diagnosis of tuberculosis in tuberculosis centre in salahaldin Governorate in 2018-2019

ABSTRACT

Tuberculosis (TB) is a communicable disease resulting from infection with *Mycobacterium tuberculosis* .Tuberculosis remain a leading cause of mortality in the world , nearly one third of the global population is infected with *Mycobacterium tuberculosis* , which is at risk of developing the disease . Iraq is considered to be a middle burden country with tuberculosis The current study was done on (125) patients suffered from symptoms of pulmonary TB, the information collected from center records in order to comparison between the results of GeneXpert test and results of direct sputum smear (AFB) for year 2018-2019.

The males were 63 (50.4%) patient with mean age of them was 40.97± 14.2 years , while the females represented 62 (49.6%) patient with mean age of them was 44.4 ± 17.1 years without significant difference between them . The early morning sputum samples for Ziehl-Neelsen stain were obtained from all patients. Which revealed positive in 7 (11.11%) male patients and 4 (6.45) of female patients.

Genexpert test for sputum samples was performed in 125 patients which was positive in 23(18.4%) patients as 14(22.22%) males and 9 (14.15%) females.

The two tests was positive in 11(8.8%) of patients.

The results of GeneXpert test and direct sputum smear statistically was not significant.

DOI: http://dx.doi.org/10.25130/mjotu.27.2021.25

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Introduction:

Tuberculosis is a communicable disease , resulting from infection with *Mycobacterium tuberculosis* whose principle reservoir is human being and also an animals [1][2].

Tuberculosis (TB) remains a leading cause of mortality in the world , nearly one third of the global population i.e two billion peoples is infected with *Mycobacterium tuberculosis*. Which is at risk of developing the disease [2].Furthermore , more than eight million people develop active tuberculosis every year [3].

More than 90% of global TB cases and death occur in the developing world , where 75% of cases are in the most economically productive age group (15-54 years).An adult with TB loses on average three to four months of work time , which results in the loss of 20-30% of annual household in come [4].

Moreover , co-infection with human immunodeficiency virus (HIV) significantly increase the risk of developing TB, 250,000 death due to TB/HIV over the world occur each year.The main reasons for the increasing burden of TB globally are ; poverty . collapse of health infrastructure weak national TB control program and the impact of HIV [5].

Iraq has an estimated population of 33 million and is considered to be amiddle burden country with TB, and occupies rank 108 globally and 7 in eastern Mediterranean region among countries with TB burden size and account for 3% of the total number of cases in the region.

There are an estimated 20,000 TB patient in Iraq. Estimated death due to TB are more than 4000 annually.According to WHO report, the estimated incidence of TB in Iraq is 45/100000 population (i.e estimated total

new TB cases in around 15000 per year, while the prevalence is 74/100000 [5][6].

The Government of Iraq was given priority to TB control , however, after the 2003 war and deteriorated security situation, the infrastructure and human capacity of effectively provide TB care were seriously damaged [7].

Furthermore , the available diagnostic tests including radiological imaging , smear microscopy , smear culture, and tissue biobsy [8].

While technological advances have brought about largely incremental improvement, ,more profound change may be seen with new or expected diagnostics , particularly nucleic acid amplification technologies (NAAT)[9].In 2010 , WHO accepted GeneXpert test MTB/RIF (Mycobacterial tuberculosis /Rifampicin) as a diagnostic test, it is an automated, benchtop device that tests for TB and rifampicin. It gives results within hours, is relatively easy to use and can be used at decentralized health level [10].

The purpose of this study is to compare the results of the GeneXpert test with the results of the direct sputum smear in diagnosis of pulmonary tuberculosis.

Patients and Methods:-

1- Patients :- A current study including (125) patients, (63 male) and (62 female) who attended out patient clinic of chest disease in salahaldin Governorate and its vicinity in the period from 01 January 2018 till 31 of December 2019 The information was obtained for center records and stratification according to Age groups and gender.

2- Methods

The patients were subjected to detailed history taking , clinical evaluation and number of investigations in order to

diagnosed pulmonary TB; these investigation include :-

A- Direct sputum smear examination ; for acid fast bacillin (AFB) by using Ziehl-Neelson stain (3 samples) one was taken from patient when he just reached the center.

The second and third sample were collected at early morning before breakfast. AFB smear was obtained in all patients and had sensitivity of 69.4%, specificity of 96.8%.

B- Genexpert test :-

The geneXpert test was done by take a very deep breath and hold the air for 5 second , slowly breath out then take another deep breath and cough hard until some sputum comes up into your mouth spit the sputum into the plastic cup.Adding 1.5 ml of xpert MTB/RIF sample reagent (SR) to 0.5 ml of processed sputum sample using a sterile transfer pipette and shake vigorously . then put 2 ml of this specimen into the cartridge.

The computer was turned on, and then the Genxpert instrument was turn on.

The GeneXpert shortcut icon was double using the user name and password , create text icon was chicked, the scan cartridge Barcode dialog box appears.

The GeneXpert system can identify TB bacteria from sputum samples, is also be test whether any TB bacteria present is resistant to rifampicin (RIF)- a frontiline TB drug the system is cartridge based , easy to use and provides results in 90 minutes.

The sensitivity and specificity of GeneXpert MTB / RIF varies between 82.98 and 95 % for sensitivity and 96 and 99% for specificity.

Results

The demographic features of the current study were shown in table (1).

A total of 125 cases were included in this study . The male

were 63(50.4%) patient with mean age of them was 40.97± 17.1 years with out significant difference between them.

Regording frequency of cases among different residence areas in salahaldeen Governorate , the current study reveals that most of petients were from Tikrit 77(61.6) followed by Beigi 20(16%) and shirqat 10 (8%) but less frequent in TuZe and Balad 1 (0.8%) as shown in table (2).

Furthermore , early morning sputum samples for Ziehl-Neadsen stain were obtained from all patients which revealed positive in 7(11.11%) male patients and 4(6.45%) of female patients .

This relation was statistically not significant, the total positive result were 11(8.8%) Patients as shown in table (3).

Genexpert for sputum samples was performed in 125 patients which was positive in 23(18.4%) patients as 14(22.22%) males and 9 (14.15%) females.

The two tests was positive in 11(8.8%) of patients . this relation was statistically not significant as shown in table (3).

Table (1) Frequency of cases according to age groups and sex of patients

Age / Years	**Sex**		**Total**
	Males	**Females**	
0-9	2	3	5
	3.17%	4.83%	4%
10-19	6	9	15
	9.52%	14.51%	12%
20-29	2	8	10

	3.17%	12.90%	8%
30-39	12	9	21
	19.04%	14.51%	16.8%
40-49	11	10	21
	17.46%	16.12%	16.18%
50-59	13	10	23
	20.63%	16.12%	18.4%
≥60	17	13	30
	26.98%	20.96%	24%
Total	63%	62%	125%
	100%	100%	100%

Table (2) Frequency and percentage of cases according to Residency

Residence area	**Frequency**	**Percentage**
Tikrit	77	61.6%
Beigi	20	16%
Door	6	4.8%
Sammara	5	4%
Shirqat	10	8%
Al-alam	3	2.4%
Al-Tuze	1	0.8%
Balad	1	0.8%
Hajaj	2	1.6%
Total	125	100%

Table (3) Results of sputum smears and GeneXpert test in studied patient

Test		Males	Females	Total	P. value
Sputum for AFB	Positive	7	4	11	> 0.05 NS
		11.11%	6.45%	8.8%	
	Negative	56	58	114	
		88.88%	93.54%	91.2%	
	Total	63	62	125	
		100%	100%	100%	
Gene X pert text	Positive	14	9	23	> 0.05 NS
		22.22%	14.51%	18.4%	
	Negative	49	53	102	
		77.77%	85.48%	81.6%	
	Total	63	62	125	
		100%	100%	100%	
AFB + X pert Text	Positive	Negative	Total		> 0.05 NS
	11	114	125		
	8.8%	91.2%	100%		

Discussion

In this study pulmonary TB was slightly more frequent in males (50.5%) than females (49.6%).

The highest percentage of males patients was study by Hatam AA *etal* in Baghdad Governorate .Also Harton KC *etal* observed TB prevalence is significantly higher among men than women in low – and middle income countries .

This could be due to more exposure of males to outside environment and the female often tried to ignore there initial symptoms due to their responsibilities towards their families as well as children.

The most age group affected by pulmonary TB in males patients was ≥ 60 years 17(26.98) patients , while the most age group of females was ≥ 60 years 13(20.96%) patients, the cause may be related to immunocompromise state , or those patients were suffered from chronic diseases, this relation was statistically significant .

Ragording frequency of pulmonary tuberculosis among different residence areas in salaheldeen Governorate this study reveals that most of patients were from Tikrit 61.6%, Beigi 16% shirqat 8% Al-Door 4% but less frequent in Tuze and Balad as 0.8%.

Many patients who are living in for areas in salahaldin Governorate usually prefer to attend and to seek medical care and advices in neighbor region even if these regions geographically related to other Governrate due to difficulties in transportation , for examples patient , of Tuze district usually go to KrikuK Governorate , and patients of Dijil usually go to Baghdad, At the same time , there are many displaced families from Aljazira, Beigi and shirgat on still living in Tikrit

city because of the security situation

In present study , early morning sputum samples for Ziehl-Nedsen stain were obtained from all patients ,which revealed positive results in 8.8% patient, however, it was still below that of who target , which is 70%.

A study done by Khattak MI and colleagues in pakistan showed 52% of patients had positive sputum AFB results .

The finding from Ethiopia revealed low case detection rate achieved as 21.6%.

Moreover , Genexpert test of sputum samples was preformed in 125 patient of present study which was positive in 23 (18.4%)

The Genexpert system has been approved by the WHO to be a widely used molecular diagnostic platform for the rapid detection of TB in several countries .

The results of some studies were different in some regions for examples the sensitivity the Gene expert assay in *M. tuberculosis* samples from south Africa and Turkay has been reported to be 92.7% and 96.3% respectively. Whereas sensitivity of the Gene xpert assay in Vietnam and Malaysia was reported to be 59% and 53% respectively.

While in other study , the sensitivity and specificity of sputum smear microscopy was 68.48% and 74.07% while PPV, NPV and diagnostic accuracy of sputum smear microscopy was 85.71% so, 85% and 70.19% respectively 92.59% However PPV, NPV and diagnostic accuracy of Gene Xpert test was 96.77% , 94.94% and 96.23% respectively .Statistically , there is no significances difference between the results of GeneXpert and direct sputum smear in diagnosis of pulmonary tuberculosis.

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