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Significance of Gene Xpert Mbt/Rif Test in Tuberculosis Diagnostics

Mamatova Nargiza Toirzhonovna [1], Ashurov Abduvaliy Abduhakimovich [2], Abduhakimov Baxrombek Abduvaliyevich [3], Akhtamova Shirin Khayrulloevna [4]

[1] assistant of the Department of Phthisiology and Pulmonology Samarkand State Medical University, Samarkand, Uzbekistan Bukhara State medical institute Bukhara, Republic of Uzbekistan

[2] Phthisiatrician of the highest category of the Samarkand regional Center for Phthisiology and Pulmonology, Samarkand, Uzbekistan

[3] student of the Faculty of Medical Prevention Samarkand State Medical University, Samarkand, Uzbekistan

[4] Student of the Faculty of Medicine Samarkand State Medical University, Samarkand, Uzbekistan

Abstract: Tuberculosis is an infectious disease, and its problem remains relevant throughout the world. It is the second leading cause of death among infectious diseases. Microscopy, culture media, and drug susceptibility testing are the standard methods used in the laboratory diagnosis of tuberculosis worldwide, but they are time-consuming processes, taking up to eight weeks to make a diagnosis. The urgent issue of modern phthisiology is the development of new fast and reliable methods of diagnosis of tuberculosis infection. In recent years, the Gene Xpert MBT/RIF system has been widely used. The purpose of the study was to determine the significance of the Gene Xpert MBT/RIF test in the diagnosis of pulmonary tuberculosis. The study showed the high specificity and relatively high sensitivity of the Gene Xpert MTB/RIF test, which showed that it can serve as an additional method in the comparative diagnosis of tuberculosis and other lung diseases. In addition, the Gene Xpert MTB/RIF test is a more effective screening method than conventional methods in reducing the time to diagnose tuberculosis, as well as in detecting rifampicin resistance. The Gene Xpert MTB/RIF is a fully automated method that helps ensure the biosafety of laboratory staff performing tuberculosis testing.

Keywords: Gene Xpert MTB/RIF, tuberculosis, patient, microscopy, culture media.

Tuberculosis is an infectious disease, and its problem remains relevant throughout the world. It is the second leading cause of death among infectious diseases. According to the World Health Organization (WHO), in 2013, 9 million people contracted tuberculosis and 1.5 million died from tuberculosis. More than 95% of TB deaths occur in low- and middle-income countries, and TB is one of the five leading causes of death among women aged 15 to 44 years [13]. In recent years, the treatment and control of tuberculosis have been seriously compromised by the increasing prevalence of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis [14].

Microscopy, culture media, and drug susceptibility testing are the standard methods used in the laboratory diagnosis of tuberculosis worldwide, but they are time-consuming procedures, taking up to eight weeks to make a diagnosis [3, 4].

The urgent issue of modern phthisiology is the development of new fast and reliable methods of diagnosis of tuberculosis infection. One of these methods is polymerase chain reaction (PCR). In recent years, this method has been widely used to quickly detect the DNA of Mycobacterium tuberculosis (MBT) in the test material, and the advantage of this method is that it can detect MBT in 50-80% of cases where the result of bacterioscopy is negative. defines [2,3,7,10]. In recent years, the Gene Xpert MBT/RIF system has been widely used (Cepheid, California). The Gene Xpert MBT/RIF test is an automated method that allows rapid detection of Mycobacterium tuberculosis DNA, and this method allows for determining the resistance of tuberculosis bacilli to rifampicin in sputum for 2 hours [4, 6, 8, 12]. The sensitivity and specificity of this test may be acceptable for the diagnosis of tuberculosis [1, 5, 9, and 11].

Purpose: to determine the importance of the Gene Xpert MBT/RIF test in the diagnosis of pulmonary tuberculosis.

Materials and research methods: The study included 122 patients who applied to the Samarkand Regional Phthisiatrics and Pulmonology Center with suspicion of pulmonary tuberculosis. There are 64 (52.5%) men; the average age of the patients is 41.4 ± 14.3. Patients submitted two sputum samples. Luminescent microscopy, inoculation in liquid nutrient media (Bactec), inoculation in Levenstein-Jensen medium, and test Gene Xpert MBT/RIF examination were performed. Drug sensitivity of MBT was determined using an automated system Bactec 960 MGIT inoculation in liquid nutrient media. Also, all patients underwent necessary examinations and were given a clinical diagnosis. Tuberculosis was confirmed in 69 (56.6%) patients and other lung diseases were detected in 53 (43.4%) patients. We estimated the probability of a positive Gene Xpert MBT/RIF test result and considered the odds ratio (IN) associated with these factors. Statistical significance was assessed using the X2 test. A reliability level of 0.05 was accepted as critical.

Research results: Of the 69 patients with confirmed tuberculosis, 36 (52.1%) had inflamed tuberculosis, 20 (28.9%) had diffuse tuberculosis, 11 (15.9%) had focal tuberculosis and 2 patients (3.1%)) fibrosing tubercle was detected. Most patients (76.2%) did not detect the release of bacteria by microscopy and culture media. It should be noted that the detection of MBT using these methods was recorded only in the group of tuberculosis. In 8 out of 69 patients (12%), the diagnosis of tuberculosis disease was determined based on the observed microscopy and the method of inoculation on nutrient media, with a positive result, in 5 (7.5%) the microscopy result was negative, and the method of inoculation on nutrient media was positive, 3 (4.3 %) patient had a positive microscopy result, and a negative result was observed in the method of inoculation in nutrient media.

Gene Xpert MBT/RIF testing detected MBT DNA in 46 (37.7%) patients. Among patients diagnosed with tuberculosis, 8 out of 8 patients (100%) with positive results of microscopy and culture media did not isolate tuberculosis-infected bacteria (microscopy and culture media yielded negative results) in 21 of 53 patients. (40%) the test showed a positive result, which undoubtedly improves the quality of tuberculosis diagnosis against the background of regular methods.

The fully automated Gene Xpert MTB/RIF molecular genetic method allows not only the detection of Mycobacterium tuberculosis but also the detection of resistance to rifampicin. The Gene Xpert MBT/RIF test detected rifampicin resistance in 24 of 46 positive test cases (52.1%). Gene Xpert MBT/RIF test showed a negative result in 52 out of 53 patients without confirmed tuberculosis, which testified to the specificity of this test. It was determined from the anamnesis that one patient with a positive test result had tuberculosis in the past.

We analyzed the relationship between the Gene Xpert MBT/RIF positive test result and various anamnesis, clinical, and laboratory parameters. A positive result of Gene Xpert MTB/RIF test with a positive result of fluorescent microscopy of sputum (IN 63.6, r = 0.0000), with a positive result of the method of culture of sputum in nutrient media (IN 25, r = 0.0000), confirmation of tuberculosis (IN 87, r = 0.0000), when tuberculosis was diagnosed as a result of hospitalization (IN 12.7, r =

0.015), the presence of intoxication syndrome (IN 6.4, r = 0.045), sputum or It was associated with the presence of tal (IN 13.1, r = 0.002), detection of lung degeneration in X-ray examination (IN 28.2, r = 0.0006).

Gene Xpert MTB/RIF has demonstrated up to 98% sensitivity and 99% specificity in the detection of Mycobacterium tuberculosis.

Conclusion: The study showed the high specificity and relatively high sensitivity of the Gene Xpert MTB/RIF test, which can serve as an additional method in the comparative diagnosis of tuberculosis and other lung diseases. In addition, the Gene Xpert MTB/RIF test is a more effective screening method than conventional methods in reducing the time to diagnose tuberculosis, as well as in detecting rifampicin resistance. Detection of resistance to rifampicin helps to prescribe adequate treatment for patients with drug-resistant tuberculosis at an early stage of the disease. The Gene Xpert MTB/RIF is a fully automated method that helps ensure the biosafety of laboratory staff performing tuberculosis testing.

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