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Consistency analysis of COVID-19 nucleic acid tests and the changes of lung CT

Jiang Zhifeng*, Aiqiao Feng, Tao Li

Xiaogan Hospital Affiliated to Wuhan University of Science and Technology, No. 6, Square Street, Xiaonan District, Xiaogan City, Hubei Province, China

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ABSTRACT

Background: COVID-19, the latest outbreak of infectious disease, has caused huge medical challenges to China and the entire globe. No unified diagnostic standard has been formulated. The initial diagnosis remains based on the positive of nucleic acid tests. However, early nucleic acid tests were identified to be negative in some patients, whereas the patients exhibited characteristic CT changes of lung, and positive test results appeared after repeated nucleic acid tests, having caused the failure to diagnose these patients early. The study aimed to delve into the relationships between initial nucleic acid testing and early lung CT changes in patients with COVID-19.

Method: In accordance with the latest COVID-19 diagnostic criteria, 69 patients diagnosed with COVID-19 treated in the infected V ward of Xiaogan Central Hospital from 2020/1/25 to 2020/2/6 were retrospectively analyzed. The consistency between the first COVID-19 nucleic acid test positive and lung CT changes was studied. In addition, the sensitivity and specificity of CT and initial nucleic acid were studied.

Result: The Kappa coefficient of initial nucleic acid positive changes and lung CT changes was -1.52 . With a positive nucleic acid test as the gold standard, the sensitivity of lung CT was 12.00 %, 95 % CI: 4.6–24.3; with the changes of CT as the gold standard, the sensitivity of nucleic acid positive was 30.16 %, 95 % CI: 19.2–43.0.

Conclusion: The consistency between the initial positive nucleic acid test and the CT changes in the lungs is poor; low sensitivity was achieved for initial nucleic acid detection and CT changes.

1. Introduction

COVID-19, as the latest outbreak of infectious diseases, has imposed great damage on China and other countries worldwide. At present, there has been no universally recognized gold standard for initial diagnosis, and its initial diagnosis still relies on nucleic acid testing. The initial nucleic acid test was negative, whereas at this time characteristic lung changes appeared, by repeated nucleic acid tests, it was positive, as a result, a considerable number of early patients have been missed. Studying the relationships between nucleic acid tests and CT changes in the lungs will help improve the diagnosis of COVID-19.

2. Methods

69 patients diagnosed with COVID-19 admitted to the Infectious V Ward of Xiaogan Central Hospital from 2020/1/25–2020/2/6 were retrospectively analyzed, including 41 males and 28 females, with the maximum age of 82 Years and the minimum age of 23 years. They had no history of lung infections before onset. Throat swabs were collected

from patients. COVID-19 nucleic acid ORF1ab gene and N gene were taken as target genes [1], and RT-PCR was adopted to detect both as positive Nucleic acid-positive indicators. If the initial nucleic acid test is negative, the test will be repeated at least once a day until the test is positive. Based on the change of sheet-shaped frosted glass/flocculation/strand-like changes in the outer band of the lungs as COVID-19 lung CT positive indicators [2] (Fig. 1). Study the consistency between CT changes and the positive of initial nucleic acid tests. At the same time, the sensitivity and specificity of CT changes were studied with the positive of nucleic acid test as the gold standard; the sensitivity and specificity of initial nucleic acid positives were studied with the CT of lung as the gold standard.

3. Results

Using the SPSS16.0 software package, Kappa coefficient was adopted to measure the consistency of nucleic acid and the changes of lung CT. The initial Kappa of positive nucleic acid changes and lung CT changes reached -1.52 (Tables 1, 2). Based on the gold standard of

* Corresponding author.

E-mail addresses: xjiang292@sina.com, 541316714@qq.com (J. Zhifeng), 1070872064@qq.com (A. Feng), 12672918@qq.com (T. Li).

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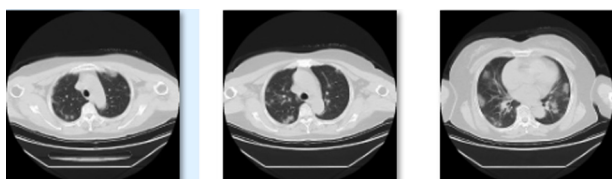


Fig. 1. xxx.

Table 1
xxx.

		CT changes in lungs		total
		No	Yes	
Initial nucleic acid test	Negative count	0	19	19
	percentage Lung CT	0.0 %	30.2 %	27.5 %
	Positive count	6	44	50
total	percentage Lung CT	100.0 %	69.8 %	72.5 %
	count	6	63	69
	percentage Lung CT	100.0 %	100.0 %	100.0 %

Table 2
xxx.

	Value	P
Kappa(K)	-.152	.051
Number of valid cases	69	

Table 3
xxx.

Criterion	Sensitivity	95 % CI	Specificity	95 % CI
< = 0 *	12.00	4.6–24.3	100.00	82.2–100.0

Table 4
xxx.

Criterion	Sensitivity	95 % CI	Specificity	95 % CI
< = 0 *	30.16	19.2–43.0	100.00	54.1–100.0

nucleic acid PCR tests, the sensitivity of lung CT was 12.00 %, 95 % CI: 4.6–24.3, specificity was 100 %, and 95 % CI:82 – 100 (Table 3). With lung CT changes as the gold standard, nucleic acid PCR-positive sensitivity was 30.16 %, 95 % CI: 19.2–43.0, specificity was 100 %, and 95 % CI: 54.1–100 (Table 4).

4. Conclusion

There is no exact consistency between the initial positive nucleic acid test and CT changes in the lungs. By employing a positive nucleic acid test as the gold standard for initial diagnosis, the sensitivity of CT changes in the lung is low; using the CT change of the lung as the gold standard, the sensitivity of positive nucleic acid tests is low as well. If the initial nucleic acid test acts as a diagnostic indicator, numerous confirmed patients will be missed. The initial diagnosis should be performed in combination with nucleic acid tests and CT changes of lung.

5. Discussion

As the latest outbreak of infectious diseases, there has been no unified diagnostic standard for the diagnosis of COVID-19. The latest Chinese standards were split into suspected cases and confirmed cases [3]. The diagnosis of suspected cases should be combined with

epidemiological history and clinical manifestations. Epidemiological history includes: 1. history of travel or residence in the affected area; 2. history of contact with patients from epidemic areas with fever or respiratory symptoms or COVID-19; 3. aggressive onset [2]. Clinical manifestations consist of: 1 fever or respiratory symptoms; 2. characteristic lung imaging changes [2]. 3. The total number of white blood cells is normal or decreases in the early stage of onset, or the lymphocyte count decreases. The diagnostic criteria for suspected cases comply with any one of the epidemiological history and any two of the clinical manifestations. A suspected case with one of the following pathogenic evidence refers to a confirmed case: 1. PCR tests of COVID-19 nucleic acid positive for respiratory specimens or blood specimens [4]. 2. Respiratory or blood specimen virus gene sequencing is significantly homologous with known COVID-19 [2]. However, in numerous patients, the initial nucleic acid test was identified to be negative, and some patients were positive after repeating the test for 5 times. Before the nucleic acid was positive, the changes of CT has occurred in lung.

The results suggested that the initial nucleic acid positivity was not consistent with variations in lung CT, and low initial nucleic acid positivity rate was achieved. If with the positivity of initial nucleic acid acts as the gold standard, the sensitivity of characteristic lung CT changes will be only 12 %, which will cause huge interference or even misleading to clinical work; as a result, diagnosis and treatment will be delayed, and even the potential patient will not be isolated in time, thereby causing the spread of the virus. If the characteristic lung CT changes are adopted as the gold standard, the sensitivity of the initial nucleic acid test will be 30.16 %, which is still low. The cause of this situation is still related to the low positive rate of initial nucleic acid test.

This study considers that the causes of the low sensitivity of the initial nucleic acid test include the method of sample acquisition, the time of acquisition, as well as the reagents used for test, which will adversely affect the test results and decrease the positive rate.

This study aimed to explore the relationships between positive initial nucleic acid test and the consistency of lung CT changes, as an attempt to facilitate the effective screening of suspected patients. No in-depth analysis is conducted on the consistency of positive nucleic acid changes and lung CT changes after repeated nucleic acid tests, which requires further research.

In conclusion, there is poor consistency between the positive rate of initial nucleic acid test and the changes of lung CT in patients with COVID-19, and initial nucleic acid test exhibits low sensitivity. This study suggests that patients with negative initial nucleic acid test and lung CT changes should be isolated at an early stage, and repeated nucleic acid test is required.

reference

[5].

CRedit authorship contribution statement

Jiang Zhifeng: Conceptualization, Methodology, Data curation, Writing - original draft, Writing - review & editing. **Aiqiao Feng:** Conceptualization, Methodology, Investigation. **Tao Li:** Methodology, Data curation, Software.

Declaration of Competing Interest

The authors declare there are not competing interests, no funding conflict.

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