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Positive rate of RT-PCR detection of SARS-CoV-2 infection in 4880 cases from one hospital in Wuhan, China, from Jan to Feb 2020

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\textbf{ABSTRACT}

\textbf{Background:} There’s an outbreak of a novel coronavirus (SARS-CoV-2) infection since December 2019, first in China, and currently with more than 80 thousand confirmed infection globally in 29 countries till March 2, 2020. Identification, isolation and caring for patients early are essential to limit human-to-human transmission including reducing secondary infections among close contacts and health care workers, preventing transmission amplification events. The RT-PCR detection of viral nucleic acid test (NAT) was one of the most quickly established laboratory diagnosis method in a novel viral pandemic, just as in this COVID-19 outbreak.

\textbf{Methods:} 4880 cases that had respiratory infection symptoms or close contact with COVID-19 patients in hospital in Wuhan, China, were tested for SARS-CoV-2 infection by use of quantitative RT-PCR (qRT-PCR) on samples from the respiratory tract. Positive rates were calculated in groups divided by genders or ages.

\textbf{Results:} The positive rate was about 38\% for the total 4880 specimens. Male and older population had a significant higher positive rates. However, 57\% was positive among the specimens from the Fever Clinics. Binary logistic regression analysis showed that age, not gender, was the risk factor for SARS-CoV-2 infection in fever clinics.

\textbf{Conclusions:} Therefore, we concluded that viral NAT played an important role in identifying SARS-CoV-2 infection.

\section{1. Introduction}

Since December 2019, an epidemic Coronavirus disease (COVID-19) caused by novel coronavirus (SARS-CoV-2) infection has occurred unexpectedly in China. Till March 2, 2020, more than 80 thousand confirmed cases have been reported in China. Of these cases, 49 thousand were identified in Wuhan City. Identification, isolation and caring for patients early are essential to limit human-to-human transmission including reducing secondary infections among close contacts and health care workers, preventing transmission amplification events. Following the national recommendations for diagnosis and treatment of pneumonia caused by 2019-nCoV (the 5th edition) and current status of clinical practice in Hubei Province, RT-PCR analysis was used to detect the causative virus from respiratory secretions. However, some investigators and clinical doctors argued that CT imaging should be served to identify the SARS-CoV-2 infection instead, since quite a bit cases showed progressive multiple peripheral ground-glass opacities in both lungs even the RT-PCR results were negative \cite{1,2}.

Since RT-PCR was one of the most quickly established laboratory diagnosis method in a novel viral pandemic, just as this COVID-19, it served efficiently to confirm a viral infection within 2 h. During the early Feb, the need of detect increased dramatically up to 10 thousands of samples per day in Wuhan City. But to what extend was this RT-PCR based viral nucleic acid test (NAT) could reflect the real SARS-CoV-2 infection?

Therefore in this study, we retrospectively analysed NAT test of 4880 cases from Jan 22 to Feb 14, 2020 in Renmin Hospital of Wuhan University. All the cases were suspected of SARS-CoV-2 infection because of, (1) typical respiratory infection symptoms such as fever, cough and dyspnoea, or (2) close contact with a COVID-19 patient. RT-
PCR were performed to detect ORF1ab and NP genes fragments from respiratory specimens, including nasal and pharyngeal swabs (NPS), bronchoalveolar lavage fluid (BLF) and sputum.

2. Materials and methods

2.1. Data collection

4880 cases from Jan 22 to Feb 14 were tested for SARS-CoV-2 infection in Renmin Hospital of Wuhan University, who were suspected or at high risk of infection because of, (1) typical respiratory infection symptoms such as fever, cough and hard breath, or (2) close contact at high risk of infection because of, (1) typical respiratory infection in Renmin Hospital of Wuhan University, who were suspected or

Table 1

| Nuclear Acid | Sputum (n = 57) | Bronchoalveolar Lavage Fluid (n = 5) | Nasal and Pharyngeal Swabs (n = 4818) | Total  | Total Positive Rate |
|--------------|----------------|-------------------------------------|-------------------------------------|--------|-------------------|
| n            | Positive Rate  | n                                   | Positive Rate                       | n      | Positive Rate     |
| NP           | 28             | 49.12%                              | 4                                   | 80.00% | 1910              |
| ORF1ab       | 29             | 50.88%                              | 5                                   | 100.00%| 1966              |
| Double positive | 28             | 49.12%                              | 4                                   | 80.00% | 1843              |

Table 2

| Nuclear Acid | Male (n = 2251) | Female (n = 2629) | χ² p value |
|--------------|----------------|------------------|-----------|
| n            | Positive Rate  | n                | Positive Rate |
| NP           | 943            | 41.89%           | 999       | 38.00% | 7.672  | 0.006   |
| ORF1ab       | 967            | 42.96%           | 1033      | 39.29% | 6.739  | 0.009   |
| Double positive | 910            | 40.43%           | 965       | 36.71% | 7.095  | 0.008   |

4. Results

4.1. Nasal and pharyngeal swabs showed poor positive rate in 4880 cases

1875 out of 4880 (38.42%) were positive by RT-PCR-based NAT test with their respiratory specimens. Among this, 39.80% were positive for SARS-CoV-2-NP and 40.98% for SARS-CoV-2-ORF1ab (Table 1). We could see that the bronchoalveolar lavage fluid (BLF), exhibited the most highest positive rate of 100% for SARS-CoV-2 ORF1ab gene (n = 5). The nasal and pharyngeal swabs (NPS) samples (n = 4818) showed a poor positive rate of 38.25%. The Sputum exhibited a 49.12% positive rate.

Table 3

| Nuclear Acid | 18–29 (n = 482) | 30–39 (n = 1097) | 40–49 (n = 841) | 50–59 (n = 1011) | 60–69 (n = 886) | ≥70 (n = 563) | χ² p value |
|--------------|----------------|------------------|----------------|-----------------|---------------|-------------|-----------|
| Gender rate  |                |                  |                |                 |               |             |           |
| (M/F)        |                |                  |                |                 |               |             |           |
| sCoV-NP      | 129            | 280              | 287            | 446             | 439           | 361         | 320.802 < 0.001 |
| sCoV-ORF1ab  | 124            | 286              | 296            | 461             | 466           | 367         | 353.547 < 0.001 |
| Double Positive | 120            | 271              | 278            | 434             | 424           | 348         | 306.946 < 0.001 |
| Double Positive Rate | 24.90% | 24.70% | 33.05% | 42.93% | 47.86% | 61.81% |

3.1. Statistical analysis

Statistical analyses were done by using the SPSS25.0 software. Chi-square test was used to compare inter-group differences, and binary logistic regression analysis was performed to analyze the risk factors for SARS-CoV-2 prevalence. Statistical significance was defined as P < 0.05.
4.3. The positive rate increased in older cases

When we analyzed the positive rate according to age (Table 3), and we could see that positive rate increased from 24.90% (age 18–30) to 61.81% (age > 70).

4.4. Gender and age are two risk factors for SARS-CoV-2 infection

Binary logistic regression analysis showed that gender and age were two risk factor for SARS-CoV-2 infection (Table 4). Male and older people were more sensitive to the this novel virus infection (p < 0.05).

4.5. Specimens from Fever Clinics exhibited significant higher positive rate

Why the positive rate in this 4880 cases were this low? Or did the viral NAT test fail to serve for the diagnosis in this pneumonia epidemic? Since the 4880 specimens conclude all cases during the period in the hospital, such as fever, cough and hard breath, or close contact with COVID-19 patient, we further analyzed data from adult fever clinics (n = 1707, Table 5). Notably, the positive rate of patients in fever clinics (57.00%) was significantly higher than the rate of the total (38.42%).

5. Discussion

For the 2019 novel coronavirus disease (COVID-19), patients can be afebrile in the early stages of infection, with only chills and respiratory symptoms, but not always high temperature[4–6]. Elevated C-reactive protein (CRP) and lymphopenia are important factors. More and more evidence had shown distinct and complicated performance of COVID-19 as compared to SARS or MERS, which provided typical clinical symptoms for diagnosis [5]. Therefore, diagnosis of suspected SARS-CoV-2 caused pneumonia in Wuhan was based on clinical characteristics, chest imaging [1,7], and the ruling out of common bacterial and viral pathogens that cause pneumonia as suggested by the latest National recommendations for diagnosis and treatment of pneumonia caused by 2019-nCoV (the 6th edition).

Here in this study, we analyzed recent 4880 cases by laboratory diagnosis of suspect SARS-CoV-2 infection in one hospital in Wuhan City, showing 38.42% positive percentage for total, but 57.00% positive
in Fever Clinics. Relatively increased positive percentage in Fever Clinics suggested that the fever associated clinical symptoms were linked with viral NAT, at some degree. Interestingly, total positive percentage were associated with gender and age, while positive percentage in Fever Clinics was only associated with age, not gender. Therefore, consistent with other reports, we could conclude that for suspect SARS-CoV-2 infection, positive percentage would be higher in Male and Old, but in Fever Clinics, gender was not a risk factor. The epidemic seems to be spreading rapidly worldwide, especially in Korea, Italy and Iran. Based on the reasons mentioned above, we suggest that viral NAT is a rapid, easy conducted, and widely used laboratory diagnosis for SARS-CoV-2 infection, especially for Fever Clinics. Clinical characteristics, chest imaging and etiology testing based on viral genes RT-PCR should be combined to tell a confirmation [4,8]. Since there exists infection with atypical symptoms, RT-PCR should be taken for several times just in case of fake negative results.

For those countries who are facing an increased number of SARS-CoV-2 infection, we strongly suggest to prepare more reagents for SARS-CoV-2 NAT. Also, more laboratories and facilities should be trained and prepared for RT-PCR detection under a Biological Safety Protection 3-Level, just in case the horrible increasing requirements for detection that happened in early Feb in Wuhan, China.

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Author contributions

Y.F and C.L.Z designed the study and analyzed the data. R.L and H.H collected and analyzed the data. F.L., Z.H.L., Y.L.L., and K.L.W wrote the paper. Y.F and C.L.Z read and approved the final manuscript.

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