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## A Survey for COVID-19 among HIV/AIDS Patients in Two Districts of Wuhan, China --Manuscript Draft--

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<b>Abstract:</b>	<p><b>Background</b> There were over 49 thousand Coronavirus infected diseases-19(COVID-19) patients in Wuhan city, Hubei province, China, the center of epidemic of the disease. Over 5000 HIV/AIDS patients live in Wuhan. No data on the morbidity of COVID-19 in HIV/AIDS patients have been published to date.</p> <p><b>Methods</b> In this study, we investigated 1178 HIV/AIDS patients in two central districts in Wuhan city. Whether they have any clinical presentations and whether they contacted any confirmed COVID-19 patients were inquired. The results for nucleic acid test (NAT) of SARS-CoV-2 and CT scan in those with clinical symptoms or contact history were investigated. The antiretroviral regimens of all these patients and other information, like age, sex, CD4+T cell counts (CD4 counts), HIV viral load (HIV-VL) were also collected. The risk factors for the COVID-19 in HIV/AIDS patients were analyzed.</p> <p><b>Findings</b> We found 12 individuals in 1174 HIV/AIDS patients who presented clinical symptoms, and 8 of them were confirmed COVID-19. Six of them were NAT confirmed SARS-CoV-2 infection, and 2 were clinical confirmed cases. Six of the 8 COVID-19 patients had CD4 counts &gt; 350/μl, and 2 with CD4 counts between 101-350/μl. All of the 8 patients have a low HIV-VL &lt; 20 copies/ml. The older age is the risk factor to occur COVID-19 in HIV/AIDS. All the 8 COVID-19 patients were from 947 individuals (0.84%) who took NRTI+NNRTI as antiretroviral regimen. In those who have no symptoms, there were another 9 HIV/AIDS patients had close contact with confirmed COVID-19 patients, and only 1 of them was confirmed positive by NAT.</p> <p><b>Interpretation</b> Our findings indicated that the compromised immunity might be the reason that HIV/AIDS patients did not occur inflammatory changes and clinical symptoms, which support the early usage of corticosteroids in treatment for COVID-19. At the same time, the usage of LPV/r may potentially help to prevent or treat COVID-19.</p>

# A Survey for COVID-19 among HIV/AIDS Patients in Two Districts of Wuhan, China

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## Introduction

As of 2<sup>nd</sup> March 2020, a total of more than 80,000 of the Coronavirus infected disease-2019 (COVID-19) patients have been reported in China. More than 49,300 were in Wuhan, Hubei Province, which is the original epidemic region, and 2227 Wuhan citizens died of this disease<sup>1</sup>. The virus was transmitted from human to human at an astonishing speed. By 25<sup>th</sup> Jan, the basic reproductive number  $R_0$  was estimated to be 2.2-2.68, and the estimated infected number in Wuhan is as huge as 75,000 by a statistical model<sup>2-4</sup>. Although the current reported total number of COVID-19 patients in Wuhan is less than this estimated one due to the effective measures Chinese government has taken, there are still hundreds of newly occurred cases come out each day in Wuhan. One of the reasons for the higher infectiousness of COVID-19 than severe acute respiratory syndrome (SARS) is that the apparent clinical presentations of COVID-19 is much more variable than SARS and there are even the asymptomatic SARS-CoV-2 infectors, no mention the positive rate of nucleic acid test (NAT) is only ~50%, which increase the difficulty for the diagnosis and the corresponding solutions<sup>5</sup>.

Several studies have summarized the clinical characteristics of COVID-19<sup>6-8</sup>, some have reported that the chronic basic diseases, like hypertension, atherosclerosis, and diabetes, etc, the patients have had previously may relevant with the severity of the disease<sup>7-10</sup>. But up till now, none study has been conducted to evaluate the morbidity and severity of COVID-19 in HIV/AIDS, in which patients are with a compromised immunity and also in a chronic disease state. Actually, HIV/AIDS patients were presumed to be at the higher risk of getting infected by the novel virus, for their susceptibility to even opportunistic pathogens.

At present, there is no vaccine or effective antiviral treatment for COVID-19, to identify a useful medication as soon as possible is critical for controlling the increasing huge number of severe cases (more than 14 thousand in whole China and 10 thousand in Wuhan). Remdesivir, Lopinavir/Ritonavir (LPV/r), Ribavirin, Arbidor, and Chloroquine, etc, have already been tried in COVID-19 treatment, and Remdesivir is now under a registered clinical experiment. The combination protease

inhibitor, LPV/r, was proved to target both HIV and coronaviruses<sup>11</sup>, and the national guidelines for diagnosis and treatment of COVID-19 (from the 1<sup>st</sup>-6<sup>th</sup>) also suggested to treat patients with LPV/r. The exact effect of LPV/r in treating the SARS-CoV-2 caused disease still need more observation. But since HIV/AIDS patients might take LPV/r as a routine of the antiretrovirus therapy (ART), it provides us a natural study object to observe whether LPV/r can be used as a pre-exposure prophylaxis (PrEP) for SARS-CoV-2, like the PrEP for HIV, people who do not infected with HIV but at high risks can take antiretroviral drug every day to prevent the infection.

Therefore, in this study, we investigated 1178 HIV/AIDS patients in Wuhan and surveyed their health status and whether they were directly contacted with confirmed COVID-19 patients. The percentage of COVID-19 patients with clinical symptoms in this cohort was calculated. The association between the occurrence of COVID-19 and the patient's ART, HIV viral load (HIV-VL), and CD4+T cell counts (CD4 counts) were analyzed. By this investigation, we hope to find out the risk factors of COVID-19 in HIV/AIDS population, and evaluate the role of ART in preventing or treating COVID-19.

## **Materials and Methods**

### *Patients in two districts of Wuhan*

Wuhan city covers an area of 8659.15 square kilometers. The permanent resident population of Wuhan is about 9083, 500, and the migration population is about 5103, 000. There were 5953 individuals in total with HIV (till the date of 31th Oct. 2019) living in Wuhan. There are 13 districts in Wuhan, among them, Wuchang district covers the area of 64.58 square kilometers and have permanent resident population as 1276, 300. While Qingshan district covers the area of 57.12 square kilometers, and have permanent resident population as 528, 800. Up till February 27<sup>th</sup>, the total number of COVID-19 patients in Wuchang and Hongshan district was 8032 (17.09% in all COVID-19 cases in Wuhan), and 2924 (6.22% in all COVID-19 cases in Wuhan) respectively. The HIV/AIDS patients in Wuchang and Qingshan district was 913 (15.33% in all HIV/AIDS cases in Wuhan) and 265 (4.45% in all HIV/AIDS cases in Wuhan), respectively. (The map of Wuhan city and the distribution of COVID-19 and HIV/AIDS patients in Wuchang and Qingshan districts were illustrated in figure 1).

### *The scheme of the investigation*

1178 HIV/AIDS patients in the two districts were investigated by telephone (or social communicate software) but not face to face interview because the city had to comply to lockdown and the individuals were quarantined in their residence community. In all HIV/AIDS patients, 4 were living abroad for at least 6 months and thus were ruled out from the study.

Whether the patients had typical symptoms those were mentioned in the previous clinical reports like fever, non-productive cough, dyspnea, myalgia, and diarrhea, etc<sup>10</sup>, were firstly inquired. And whether they had contacted with confirmed or suspected COVID-19 patients were then inquired. For those who presented with clinical symptoms or had contacted COVID-19 patients, they were introduced to go to local designated hospital for receiving CT scan and virus nucleic acid test (NAT).

To avoid probable mistakes about information of any patient, we also double checked the name and identification card number of each enrolled HIV/AIDS patient

and that of the COVID-19 patients in the information management systems of two districts' Center for Disease Control and Prevention.

### *Diagnosis of COVID-19*

Due to the lower positive rate of NAT than the actual infection, according to the Chinese 5<sup>th</sup> edition of COVID-19 diagnosis and treatment guideline<sup>12</sup>, those who lived in Wuhan, either positive for NAT or having typical changes on CT image<sup>13</sup> and the clinical symptoms were considered as confirmed COVID-19. In this study we followed this guideline. For those who don't have any symptoms but only positive for NAT and detect referred them as inapparent infectors.

### *Laboratory results acquisition*

The NATs for SARS-COV-2 were performed in the local designated hospital that used the laryngeal swab specimens and the real-time reverse transcription polymerase chain reaction as reported previously<sup>9</sup>. The patients' CD4 counts, HIV-VL in recent 3 months, regimen of ART and other information were obtained from the AIDS Comprehensive Prevention and Control Data Information Management System of Chinese Center for Disease Control and Prevention.

### *Statistical analysis*

Continuous variables were presented as median (Interquartile range, IQR), and compared using the Wilcoxon rank-sum test; categorical variables were presented as count (%), and compared using the Fisher's exact test. Risk factors for COVID-19 in HIV/AIDS were analyzed by the Logistic regression. We performed all statistical analyses using SAS 8.02 and a significance level of 0.05.

## Results

### *1. There were 8 COVID-19 out of 1174 investigated HIV/AIDS patients.*

Our investigators surveyed 1174 HIV+ individuals who were recorded in the the AIDS Comprehensive Prevention and Control Data Information Management System of Chinese Center for Disease Control and Prevention. We found 12 HIV/AIDS individuals who presented clinical symptoms, and 8 of them were confirmed COVID-19. Moreover, 6 of them were laboratory confirmed SARS-CoV-2 infection by both CT scan and NAT, and 2 were clinical confirmed cases by CT scan only (NATs were negative). Among these 8 patients, 7 were males (88%) and 1 was female (13%). Similarly, in 1166 other HIV/AIDS patients who didn't report any typical symptoms of COVID-19, 1045 were males (90%) and 121 were females (10%). The rate of COVID-19 in people with HIV/AIDS was about 0.68% (95%CI: 0.29% - 1.34%), a little higher than the morbidity of population in Wuhan (~0.5%, as 49 thousand out of 9 million according to the report by the end of February 27, 2020), while less than the estimated morbidity as 0.83% (75 thousand out of 9 million)<sup>4</sup>. Till March 3, 2020, 6 of the COVID-19/HIV patients were mild cases, 1 was severe cases, and 1 was critical case who died.

According to our survey, among those without any symptoms, another 9 HIV/AIDS patients reported close contact with confirmed or suspected COVID-19 patients. Only 1 of them was NAT positive (inapparent infector), who was with a CD4 counts as 27/ $\mu$ l. This individual occurred Kaposi's sarcoma, and was under chemotherapy. The ART of this patient had started just one month before accepting the investigation. The investigation scheme is summarized in Fig.2.

### *2. Comparison of characteristics between HIV/AIDS individuals with COVID-19 or not*

As shown in Table 1, we compared the characteristics between HIV/AIDS individuals with COVID-19 or not. The median age of these COVID-19 patients (n=8) was 57.0 years old (47.5-61.5), which was significantly (P=0.010) older than the age (36.0, 30.0-51.0) of those without COVID-19 (n=1166). This finding was consistent

with that the elder males had a higher infection rate of SARS-CoV-2 in HIV negative population.<sup>9,10,14</sup>

We next analyzed laboratory features of these 8 apparent COVID-19 HIV/AIDS patients. Six of them had CD4 counts >350/ $\mu$ l, and 2 with CD4 counts between 101-350/ $\mu$ l. Intriguingly, in 41 AIDS patients who had low CD4 counts under 100/ $\mu$ l, no one had reported any typical COVID-19 symptoms.

When we analyzed the HIV-VL of these 8 COVID-19/HIV patients, we found all of them have a low HIV-VL as less than 20 copies/ml. There were no positive symptoms were reported in 295 AIDS patients who had virus loads more than 20 copies/ml.

It's worth noting that all 8 COVID-19 patients' ARV regimens are Nucleoside Reverse Transcriptase Inhibitors (NRTIs) and Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs). While in the patients who haven't started ART, or who were taking protease inhibitor (PI), like LPV/r, Elvitegravir/cobi (EVG/c), or who were taking integrase inhibitors, like Dolutegravir (DTG), Raltegravir (RAL), and Bictegravir (BIC), there were no COVID-19 being reported. But there was no significant difference for the morbidity of COVID-19 between the patients taking each ART regimen. While 28 individuals who did not start ART were temporarily "waived" by COVID-19.

### 3. Analysis of risk factors for the occurrence of COVID-19

We then analyzed the relevance of some risk factors for the occurrence of COVID-19 using Logistic regression. We found that only the age of the patients showed significant relevance with the occurrence of COVID-19 ( $P < 0.05$ ), ie, like we observed above, the older patients might have more chance to occur COVID-19. Other factors, no matter the gender or the CD4 counts, or the HIV-VL, or the ART regimen didn't show any relevance with the occurrence of COVID-19.



## Discussion

The epidemic of COVID-19 has been outbreaking in Wuhan, Hubei Province, and soon spreading to whole China since January 2020<sup>6,15</sup>. Although after taking the emergent strategies, the number of newly occurred COVID-19 in China is decline, the total infected number in Wuhan city and Hubei province is still extraordinarily huge. Moreover, there are more sparks of newly occurred cases in Korea, Iran, Japan, and Singapore, etc, which indicate a probability of a global pandemic.

Although it is now broadly accepted that SARS-COV-2, as an airborne pathogen, majorly cause pulmonary infection and further lesion, because 1) most of the patients presented with significant respiratory symptoms; 2) by analyzing the structure of SARS-COV-2, the characteristic SPIKE protein on the virus can bind to the angiotensin-converting enzyme 2 (ACE2)<sup>16</sup>, which broadly expressed on the epithelial cells of the lung. While since more and more patients were investigated, symptoms indicated multiple organ injuries were found, like palpitation, which indicated heart involvement, and diarrhea, which indicated abnormal intestine function<sup>17</sup>. Whether these organs lesion were attacked by the virus directly or by other mechanisms is unclear. Actually, according to the clinical characteristics, many cases presented extremely abnormal white blood cell numbers and lymphocyte counts, which indicated that inflammatory responses caused by the virus may be violent. The pathological findings also showed there were a lot of inflammatory cells being found infiltration in the lungs, the heart and liver of the COVID-19 patients<sup>18,19</sup>. The pathogenesis of COVID-19 is still unclear, but it seems that so called “inflammatory storm” may play a role in SARS-COV-2 caused multi-organ injury.

In this situation, at high risk of SARS-COV-2 infection in Wuhan City, individuals with HIV naturally served as an immune suppress model for us to recognize how the immune system work in duration of SARS-COV-2 infection. In our study, HIV/AIDS population exhibits a relatively “normal” positive rate on occurring COVID-19 but not a higher rate, unexpectedly. We observed the 8 COVID-19 patients from 1174 HIV+ individuals. Of note, all of these 8 COVID-19/HIV patients had a feature of low HIV-VL (<20 copies/ml) but relatively

higher or normal CD4 counts than other patients. This finding strongly suggested that a relatively normal immune system probably facilitates the dominant infection, or more accurately, causes the pathological changes to give rise to the symptoms.

On the other hand, our finding also indicated that a compromised immune system with a lower CD4 counts level might waive clinical symptoms. Considering there were a lot of asymptomatic SARS-COV-2 infected individuals being reported, although we don't have effective strategies to screening all of the HIV/AIDS patients, we may speculate that some of them may be actually infected but present with no symptoms. This finding probably supports the hypothesis that a lower active immune status might protect the human body from a severe viral attack other than the immune storm, such as SARS and middle east respiratory syndrome (MERS). In this context, although experts objected the usage of corticosteroids in treatment with COVID-19<sup>20</sup>, the Chinese national recommendations for diagnosis and treatment of COVID-19 (from the 1<sup>st</sup>-6<sup>th</sup>) prefer this anti-inflammatory treatment in short time for the patients with rapid progress for preventing severe multi-organ injury .

Given the scale and rapid spread of the SARS-CoV-2, there is an immediate need for medicines that help to deal with the disease before effective vaccine being available. Some medicines (Atazanavir, LPV/r, DTG, etc) were recommended by researchers performing drug screening models<sup>21,22</sup>. Meanwhile, some potential effective medicines (LPV/r, Remdesivir, Darunavir, etc) were used in clinic or clinical trial to treat COVID-19. Especially for LPV/r, a protease inhibitor, is recommended by national recommendations for diagnosis and treatment of COVID-19 (from the 1<sup>st</sup>-6<sup>th</sup>) based on its history of treating SARS and MERS<sup>23,24</sup>. To be noticeable, in this study, we reported firstly that the 8 COVID-19 patients were from 947 individuals (0.84%) who took NRTI+NNRTI as ART regimen. This rate is higher than morbidity of population in Wuhan (~0.5%, as 47 thousand out of 9 million according to the report by the end of February 27, 2020), while similar with the estimated morbidity as 0.83%, as 75 thousand out of 9 million<sup>4</sup>. This result indicates that NRTI+NNRTI could not prevent or treat COVID-19, which keeps consistent with the main results of drug screening experiments. While in 178 HIV/AIDS who took LPV/r (119 cases) or DTG

(59 cases) based ART regimen, no one occurred COVID-19. Although Lpv/r based ART regimen failed to achieve statistical significance to predict decreasing occurrence of COVID-19 by the logistic regression analysis, the finding that no COVID-19 was reported in immunodeficient population who took LPV/r still hold a great promise. We also suggest here some anti-HIV drugs, such as LPV/r, had the potential to be used as PrEP or treatment at early stages of the COVID-19.

In the present study, we found that in HIV/AIDS population, all of those combined COVID-19 patients had a relatively normal CD4 counts, which indicated a relatively normal immune function. None of those COVID-19/HIV patients took LPV/r based ART regimen, which seemed to support the use of LPV/r in PrEP and cope with COVID-19. To summarize, 1) we recommend to try LPV/r for PrEP of COVID-19 in those with high risk factors, like medical workers or volunteers who cope with COVID-19; 2) The usage of LPV/r should be at the early phase of the disease, for in later phase, the organ injury may cause by inflammation but not virus; 3) For the probable inflammation, anti-inflammatory treatment, like corticosteroids, may be taken into account. Our investigation based on only two districts of Wuhan, and less than two thousand individuals were enrolled, large scale investigation is still in need to illustrate this question more clearly.

#### Authors' contributions

YF and KL conceived and designed this investigation. XZ and PM helped to design the scheme of the investigation. FM and QZ collected the original data. YD analyzed the data. WG, YD, YF and KL contributed to interpretation of the data. WG, YF and KL contributed to writing of the paper.

#### Conflict of interest statements

The authors declare no conflict of interest.

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#### Ethics committee approval

This study was approved by the Zhongnan Hospital of Wuhan University institutional review board and the need for informed consent was waived.

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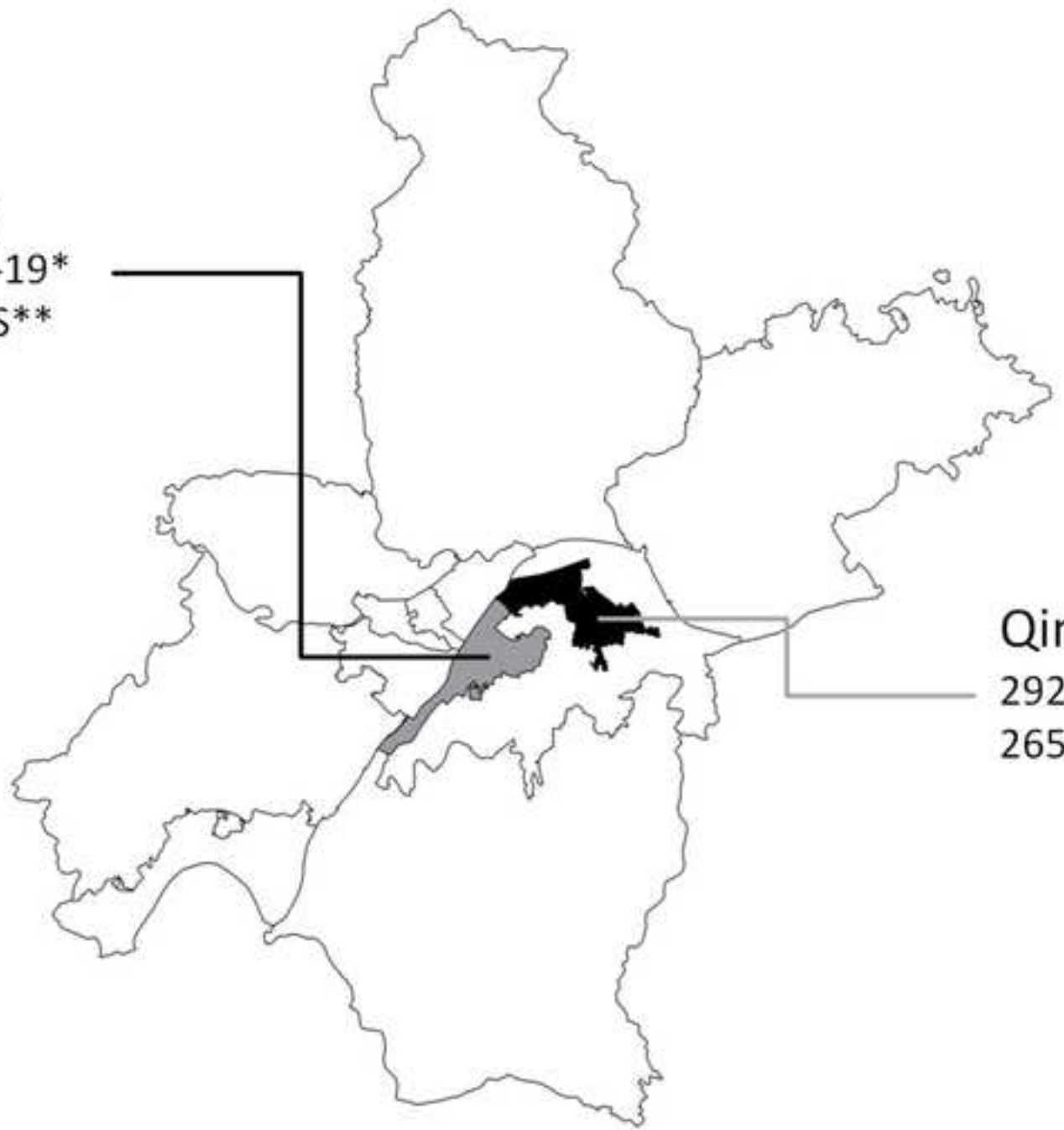
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## **Figure legend**

**Figure 1. The distribution of patients with COVID-19 and patients with HIV/AIDS in Wuchang and Qingshan districts, Wuhan.** The distribution of all documented, confirmed cases of coronavirus disease 2019 (COVID-19), and all documented patients with HIV/AIDS in Wuchang district and Qingshan district, Wuhan was shown in the figure. The numbers of HIV/AIDS patients in the two districts were obtained from the AIDS Comprehensive Prevention and Control Data Information Management System of Chinese Center for Disease Control and Prevention. The numbers of COVID-19 patients in the two districts were from the official management system of Center for Disease Control and Prevention of Wuhan by February 27, 2020.

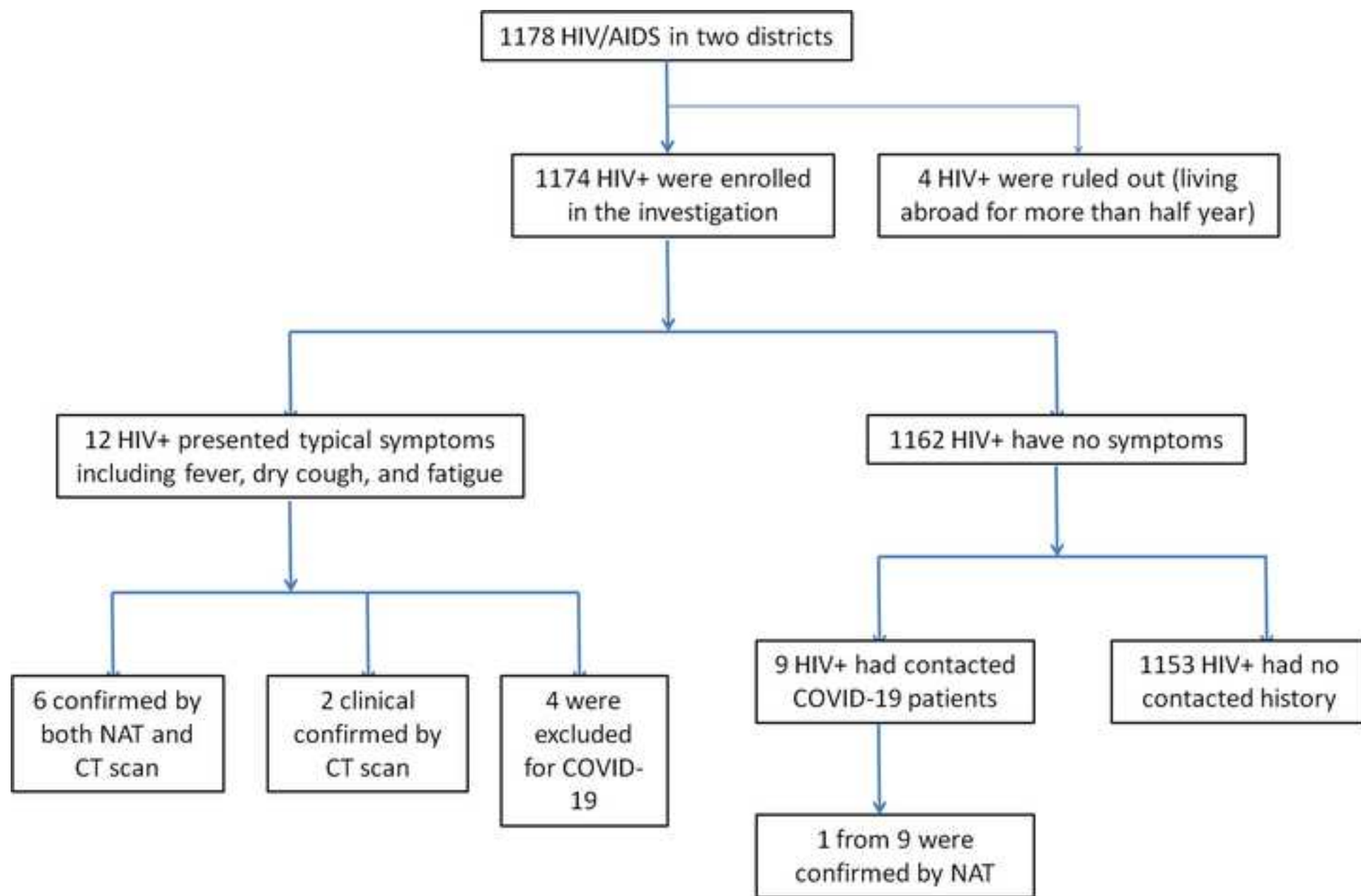
**Figure 2. The scheme of the investigation.** The investigation followed the scheme shown here. HIV/AIDS patients enrolled in this cohort are documented in the AIDS Comprehensive Prevention and Control Data Information Management System of Chinese Center for Disease Control and Prevention. The patients' information include name, sex, identification card number, HIV viral load, CD4 T cell counts, and the anti-retrovirus treatment regimen.

**Wuchang**  
8032 COVID-19\*  
913 HIV/AIDS\*\*



**Qingshan**  
2924 COVID-19\*  
265 HIV/AIDS\*\*





**Table 1\*. Comparison of characteristics between HIV/AIDS individuals with COVID-19 or not**

	Total enrolled HIV/AIDS (n=1174)	COVID-19 (n=8)	Without COVID-19 (n=1166)	P
Age (years)	36.0(30.0-51.0)	57.0(47.5-61.5)	36.0(30.0-51.0)	0.010
Gender				
Male	1052(90%)	7(88%)	1045(90%)	0.585
Female	122(10%)	1(13%)	121(10%)	
CD4 counts (cells/ $\mu$ l)	477.0(334.0-648.0)	546.0(294.5-708.5)	476.0(334.0-647.0)	0.799
$\leq$ 100	41(3%)	0(0%)	41(4%)	1.000
101-350	290(25%)	2(25%)	288(25%)	
$>$ 350	843(72%)	6(75%)	837(72%)	
Viral load (copies/ml)				
$<$ 20	879(75%)	8(100%)	871(75%)	0.213
$\geq$ 20	295(25%)	0(0%)	295(25%)	
ART regimen				
NRTI+NNRTI	947(81%)	8(100%)	939(81%)	0.820
LPV/r-based	119(10%)	0(0%)	119(10%)	
DTG-based	59(5%)	0(0%)	59(5%)	
EVG/c-based	15(1%)	0(0%)	15(1%)	
RAL or BIC-based	6(1%)	0(0%)	6(1%)	
None	28(2%)	0(0%)	28(2%)	

\*Data are median (IQR) or n (%). P values comparing HIV/AIDS individuals who had COVID-19 or not are from Wilcoxon rank-sum test or Fisher's exact test.

**Table 2. Risk factors for the occurrence of COVID-19 in the HIV/AIDS cohort**

	Univariate Logistic Regression	P	Multivariate Logistic Regression	P
	OR (95% CI)		AOR (95% CI)	
Age (years)	1.059(1.012,1.109)	0.013	1.055(1.006,1.107)	0.028
Gender				
Male	1		1	
Female	1.234(0.151,10.113)	0.845	0.964(0.115,8.117)	0.973
CD4 counts (cells/ $\mu$ l)				
$\leq$ 100	<0.001(<0.001,>999.999)	0.981	<0.001(<0.001,>999.999)	0.986
101-350	0.969(0.194,4.827)	0.969	1.020(0.191,5.450)	0.981
>350	1		1	
Viral load (copies/ml)				
<20	1		1	
$\geq$ 20	<0.001(<0.001,>999.999)	0.948	<0.001(<0.001,>999.999)	0.957
ART regimen				
NRTI+NNRTI	1		1	
LPV/r-based	<0.001(<0.001,>999.999)	0.967	<0.001(<0.001,>999.999)	0.974
DTG-based	<0.001(<0.001,>999.999)	0.977	<0.001(<0.001,>999.999)	0.982
EVG/c-based	<0.001(<0.001,>999.999)	0.988	<0.001(<0.001,>999.999)	0.991
RAL or BIC-based	<0.001(<0.001,>999.999)	0.993	<0.001(<0.001,>999.999)	0.994
None	<0.001(<0.001,>999.999)	0.984	<0.001(<0.001,>999.999)	0.989

OR=odds ratio, AOR=adjusted odds ratio, CI=confidence interval.