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Complete List of Authors:	Sawano, Toyoaki; Sendai City Medical Center, Department of Surgery Kotera, Yasuhiro; University of Derby, N/A Ozaki, Akihiko; Jyoban Hospital of Tokiwa Foundation, Department of Breast Surgery; Medical Governance Research Institute, N/A Murayama, Anju; Tohoku University School of Medicine, N/A Tanimoto, Tetsuya; Medical Governance Research Institute, N/A Sah, Ranjit; National Public Health Laboratory, N/A Wang, Jiwei; Fudan University, Institute of Epidemiology
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Original article

Underestimation of COVID-19 cases in Japan: an analysis of RT-PCR testing for COVID-19 among 47 prefectures in Japan

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Authors:

Toyoaki Sawano, MD;[1] Yasuhiro Kotera, MA;[2] Akihiko Ozaki, MD;[3, 4] Anju Murayama;[4, 5] Tetsuya Tanimoto, MD;[4] Ranjit Sah, MD;[6] Jiwei Wang, PhD.[7]

Affiliations:

1 Sendai City Medical Center, Sendai, Miyagi, Japan; Fukushima Medical University School of Medicine, Fukushima, Japan.

2 University of Derby, Derby, United Kingdom.

3 Jyoban Hospital of Tokiwa Foundation, Iwaki, Fukushima, Japan.

4 Medical Governance Research Institute, Minato-ku, Tokyo, Japan.

5 Tohoku University School of Medicine, Sendai, Miyagi, Japan.

6 National Public Health Laboratory, Kathmandu 44600, Nepal.

7 School of Public Health, Fudan University, Shanghai, China.

Corresponding author:

Toyoaki Sawano, MD, Department of Surgery, Sendai City Medical Center, 5-22-1, Tsurugaya, Miyagino-ku, Sendai, Miyagi, 983-0824, Japan; ORCiD ID: 0000-0002-1482-6618; E-mail: toyoakisawano@gmail.com; Telephone: +81-22-252-1111; FAX: +81-22-252-0454

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Drs Ozaki and Tanimoto receive personal fees from Medical Network Systems, MNES Inc., outside the submitted work. The other authors have no competing interests.

Abstract

Background: Under the unique Japanese policy to restrict reverse transcriptase-polymerase chain reaction (RT-PCR) testing against severe acute respiratory syndrome coronavirus 2, a nationwide number of its confirmed cases and mortality remains to be low. Yet the information is lacking on geographical differences of these measures and their associated factors.

Aim: Evaluation of prefecture-based geographical differences and associated predictors for the incidence and number of RT-PCR tests for COVID-19.

Design: Cross-sectional study using regression and correlation analysis.

Methods: We retrieved domestic laboratory-confirmed cases, deaths, and the number of RT-PCR testing for COVID-19 from January 15 to April 6, 2020 in 47 prefectures in Japan, using publicly-available data by the Ministry of Health, Labour and Welfare. We did descriptive analyses of these three measures and identified significant predictors for the incidence and RT-PCR testing through multiple regression analyses and correlates with the number of deaths through correlation analysis.

Results: The median prefectural-level incidence and number of RT-PCR testing per 100,000 population were 1.14 and 38.6, respectively. Multiple regression analyses revealed that significant predictors for the incidence were prefectural-level population ($p < 0.001$) and the number of RT-PCR testing ($p = 0.03$); and those for RT-PCR testing were the incidence ($p = 0.025$), available beds ($p = 0.045$) and cluster infections ($p = 0.034$).

Conclusion: Considering bidirectional association between the incidence and RT-PCR testing, there may have been an underdiagnosed population for the infection. The restraint policy for RT-PCR testing should be revisited to meet the increasing demand under the COVID-19 epidemic.

Introduction:

Since the Coronavirus Disease 2019 (COVID-19) outbreak in Wuhan, China erupted in late-2019, infection with the causative virus of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has rapidly become a significant problem worldwide.[1] During the last several months of the global response to COVID-19, it has been increasingly understood that SARS-CoV-2 has spread partly via mild symptoms and an asymptomatic population.[2] Further, COVID-19 has a relatively long incubation period among symptomatic patients.[3] This means that alongside rigorous social distancing, a liberal performance of RT-PCR testing is essential to prevent the SARS-CoV-2 from spreading, which has been gaining an increasing popularity for the response against COVID-19 globally.[4] However, such liberal approach is not accepted and remains controversial in some countries including Japan, in which a restrictive performance of RT-PR testing has been conducted mainly for severe patients with COVID-19.[5]

In this context, a case study of the Japanese response would provide significant insight toward a strategy for RT-PCR testing. In Japan, the first case was detected as early as mid-January 2020, but the epidemic curve was not steep compared with that of other countries such as Italy, South Korea, the United States, and Iran as of April 2020.[6, 7] It has been increasingly speculated that this has been caused by the Japanese central government's policy to restrict the provision of RT-PCR testing for this SARS-CoV-2.[8, 9] Alternatively, Japan has focused on testing for cluster infections of SARS-CoV-2 as a proactive epidemiological investigation, and indeed the testing provision remains moderate (1000-2000 per day nationwide in late March, 2020).[10] In this strategy, upon request from attending clinicians, bureaucrats in a local governmental healthcare center give their decision to perform any test at their discretion based on the restrictive guidelines of the central government. However, it has been reported that such requests from clinicians frequently result in rejection, and thus it is reasonable to speculate that testing number would be small and differ among regions.

Japan is composed of 47 administrative districts (prefectures), covering an area of 377,900 km^2 and a population of 126.8 million.[10] Although the population density and human flow vary substantially in each prefecture, ranging from densely populated metropolis like Tokyo to depopulating rural areas, contributing factors related to geographical differences in the incidence and mortality of COVID-19 and the provision of RT-PCR testing in each prefecture remain unknown.

In this study, it was primarily aimed to evaluate geographical differences in incidences, number of deaths, and RT-PCR testing with regard to the COVID-19. Additionally, the associated predictors were investigated for geographical differences through multiple regression analyses concerning the incidence and RT-PCR testing for COVID-19, and correlates with deaths through correlation analysis using the demographic and geographic data for each prefecture.

Methods:

Study settings and data collection

Domestic laboratory-confirmed COVID-19 cases and the total numbers of RT-PCR testing conducted from January 15, 2020, (the day when the first case of COVID-19 in Japan was documented in the governmental report) to April 6, 2020, were collected in 47 prefectures in Japan, using publicly available data from the Ministry of Health, Labour and Welfare (MHLW). The MHLW initiated the RT-PCR testing using the prototype testing kit from January 14, 2020, and the development of RT-PCR testing was completed on January 21, 2020.[10]

In the publicly available data, the number of RT-PCR tests included both positive and negative cases, while the number of cases tested for a follow-up (e.g., confirmation of negativity for hospitalized patients before discharge) were not included. Domestically identified cases only were included, whereas, charter flights returnees from Wuhan, China and those quarantined on a cruise ship "Diamond Princess"' docked in Yokohama were excluded, as the aim was to focus solely on cross-prefecture comparisons.

Using the population of each prefecture as of 2018 published by Japan's Statistics Bureau,[11] the number of physicians, nurses, COVID-19 patients, and the number of RT-PCR testing per population were calculated in each prefecture. In addition, the number of available beds were obtained for specific infectious diseases, including COVID-19, which are legally categorized as type-2 in the Japanese classification, in each prefecture from the MHLW data as of April 6. Based on the data published by prefectural governments, the number of deaths due to COVID-19 for each prefecture was obtained as of April 6. Further, the number of cluster infections were obtained, defined in the MHLW report as of March 31, 2020, in each prefecture.

In addition, to take into account the influence of foreign visitors, Chinese visitors and US military facilities were accounted; the number of Chinese visitors in each prefecture using the data published by the Ministry of Land, Infrastructure, Transport and Tourism; the numbers of US Force Japan facilities using publicly available information released by the Defense Agency in each prefecture.

Data analysis

Data were first screened for outliers, which were identified using the outlier labeling rule,[12] then winsorized.[13] All variables were not normally distributed (Shapiro-Wilk's test, $p <$

.05); thus, the data were square-root-transformed to satisfy the assumption of normality *(14)*. Multiple regression analyses were conducted to identify significant predictors for the number of patients as the outcome variable.

Firstly, none of the variables were significant predictors for the number of patients when all 7 variables were considered; including the number of deaths, population, the number of patients, available beds, the number of clusters, Chinese visitors, and US Force Japan facilities. After excluding variables that were less relevant, 4 predictor variables were used in the final model; including population, the number of available beds, the number of RT-PCR tests, and the number of clusters. Multicollinearity was of no concern (VIFs < 10).

Second, the contributing factors to the number of RT-PCR tests were analyzed. We hypothesized that 5 predictor variables for the number of RT-PCR tests were the outcome variables, including the number of deaths, population, number of patients, available beds, and clusters. Multicollinearity was of no concern (VIFs < 10). Tests were done to assess whether the number of doctors, nurses, Chinese visitors, and US Force Japan facilities would predict the number of RT-PCR tests, although none of these variables did not predict the outcome significantly.

Lastly, Pearson's correlation was used to identify correlates with deaths. Five predictors were considered to explore relationships with deaths: population, the number of patients, the number of RT-PCR tests, the number of available beds, and the number of clusters.

Results:

During the study period, a total of 3,817 test-positive COVID-19 cases were reported, with an incidence of 3.0 per 100,000 population throughout Japan (median, 1.138; IQR, 0.70-

2.82). Similarly, the total number of RT-PCR tests was 48,357, and the median number of RT-PCR testing per 100,000 population was 38.6 (IQR: 25.4-48.1). Figure 1 shows the number of cases of COVID-19 and RT-PCR testing per 100,000 population in each prefecture. The incidence of COVID-19 tended to be higher in prefectures with large cities (e.g., Tokyo and Osaka). There was no apparent association between the size of cities and the number of RT-PCR tests per population. Details of the numbers of each variable in each prefecture are available in supplementary Table 1 and 2.

Table 1 shows multiple regressions predicting the number of patients in each prefecture. The 4 predictor variables accounted for 80% (adjusted R^2) of the variance for the number of patients, indicating a large effect size *(15)*. Population ($p < 0.001$) and the number of RT-PCR tests ($p = 0.03$) were significant positive predictors for the number of patients. The number of clusters was not significant ($p = 0.054$). Table 2 shows multiple regression analysis predicting the number of RT-PCR tests in each prefecture. The 5 predictor variables accounted for 74% (Adjusted R^2) of the variance for the number of RT-PCR tests, indicating a large effect size *(15)*. The number of patients ($p = 0.025$), clusters ($p = 0.034$), and available beds ($p = 0.045$) were significant positive predictors.

Table 3 shows correlation analysis identifying significant correlates with deaths; all variables were significant including, population, number of patients, tests, available beds, and clusters ($p < 0.01$). Among them, the number of patients ($r = 0.80$), population ($r = 0.73$), and number of clusters ($r = 0.70$) were strongly associated with the number of deaths.

Discussion:

As new data about COVID-19 are being released day by day, we aimed to give a timely report for COVID-19 by analyzing publicly available data with regard to COVID-19 throughout Japan, which will help better understand the regional differences in the COVID-19 situation. As of April 6, 2020, population and number of RT-PCR tests were significantly associated with the increased incidence of COVID-19 in 47 prefectures. In addition, the deaths due to COVID-19 were significantly associated with various analyzed factors, including the population and the number of clusters, alongside the incidence and RT-PCR tests. Given that Japan has adopted a unique policy to restrict the number of RT-PCR testing, these findings would provide important lessons to a strategy to counteract the spread of emerging infectious diseases, including and beyond the case of the COVID-19.

These results are reasonable because residents in densely populated prefectures such as Tokyo and Osaka would have numerous opportunities to contract COVID-19 due to limited social distancing, and an increased number of patients would lead to an increased number of deaths. Of note, the fact that the increased number of RT-PCR tests led to more detection suggests the presence of numerous underdiagnosed patients under Japan’s constrained policy for RT-PCR testing.

The number of RT-PCR was, in fact, lower in Japan than in other countries; as of April 6, the number of RT-PCR testing per 100,000 in Italy, Korea, and US was more than 1200, 900, and 500, respectively, while, that of Japan was as low as 38 as shown in this study.[16] RT-PCR testing has not been sufficiently provided to citizens in need under the policy of prioritizing RT-PCR testing to severe cases, leading to a significant concern that Japan’s official statistics underestimate the actual case number of COVID-19.

It was found that here were wide differences in the number of RT-PCR tests among prefectures, and it was significantly associated with the number of COVID-19 patients, clusters, and available beds. This would reflect a unique policy that the Japanese government has prioritized to perform RT-PCR testing for finding clusters of COVID-19 patients and related individuals who had close contact with the patients by the special projects team of the government. Although the number of available beds predicted the number of RT-PCR, given that medical institutions with such beds tend to be present in large cities, there may be confounding factors affecting the finding.

Of note, among the 47 prefectures, Wakayama prefecture had the highest number of RT-PCR testing per population (175.6 testing per 100,000), possibly because the local governor adopted a liberal and aggressive RT-PCR testing policy contrary to the central government, and it has succeeded in containment as of early April 2020. On the other hand, the prefectures with dense cities such as Tokyo and Osaka (32.0 and 19.9 testing per 100,000, respectively,) were not able to implement such an aggressive policy for RT-PCR testing, and subsequently, the number of patients is rapidly increasing, although other factors may also explain the phenomenon.

In April 2020, the number of COVID-19 patients has continued to increase in Japan, but it is not clear whether the infection has been spreading or it is just because the government has gradually changed the policy to increase the number of RT-PCR testing to find more undiagnosed cases. Actually, some institutions have started screening of individuals without definite symptoms related to COVID-19 using RT-PCR or serological testing, and found 3-6% of them could have already been exposed to SARS-CoV-2, suggesting the presence of much higher number of undiagnosed population. Given that extensive RT-PCR testing for a wider population has gradually become a consensus in containing the disease worldwide, the restricting policy for testing in Japan can be considered suboptimal.

Limitations

Several limitations are present in this study. There were other factors that could not be evaluated in the multiple regression analysis, such as access to medical care, therapeutic drugs, other diseases like influenza, detailed situations of human flow domestically and internationally, ventilators, and ICU beds. In addition, as there were only 80 deaths associated with COVID-19 at the time of our analysis, these findings should be interpreted with caution.

Conclusion:

In this study, it was primarily shown that the prefectural-level incidence and RT-PCR testing were low, and the large geographical differences in the incidence and deaths of COVID-19 and the provision of RT-PCR testing with their predictive factors in Japan. Although the incidence of COVID-19 remained low, it should be interpreted with caution since the prefectural-level number of RT-PCR testing was much smaller than that of other countries facing similar situations. The bidirectional association between the number of patients and RT-PCR may have suggested the presence of underdiagnosed patients, and it is necessary to increase the capacity of the RT-PCR testing to meet its growing demand in the country.

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Author Bio

The author (T.S) belong to the Department of Surgery at Sendai City Medical Center and the Department of Public Health at Fukushima Medical University. My main research interests are the vulnerable to healthcare after a disaster, and the author is still engaged in research on them.

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Tables

Table 1. Multiple regression predicting the number of COVID-19 patients in each prefecture

Number of COVID-19 Patients (Outcome Variable)				
Predictor Variables	B	SE_B	β	CI for B (Lower, Upper)
Population	**1.47****	0.30	0.69	0.86, 2.08
Number of Available Beds	-0.60	0.34	-0.24	-1.28, 0.07
Number of RT-PCR Testing	**0.09***	0.04	0.29	0.01, 0.17
Number of Clusters	1.22	0.62	0.20	-0.02, 2.46
Adjusted R^2	0.80			

B = Unstandardized Regression Coefficient; SE_B = Standard Error of the Coefficient, β Standardized Coefficient. CI = Confidence Interval. ***$p < 0.05$, **$p < 0.01$**

Table 2. Multiple regression predicting the RT-PCR testing of patients in each prefecture

Number of RT-PCR Testing (Outcome Variable)				
Predictor Variables	B	SE_B	β	CI for B (Lower, Upper)
Deaths	-1.51	2.28	-0.09	-6.11, 3.09
Population	0.48	1.42	0.07	-2.39, 3.35
Number of Patients	**1.39***	0.60	0.42	0.19, 2.60
Number of Available Beds	**2.61***	1.26	0.31	0.06, 5.16
Number of Clusters	**5.20***	2.37	0.26	0.42, 9.99
Adjusted R^2	0.74			

B = Unstandardized Regression Coefficient; SE_B = Standard Error of the Coefficient, β Standardized Coefficient. CI = Confidence Interval. ***$p < 0.05$***

Table 3. Correlation analysis with regards to deaths.

	Deaths
Population	0.73**
Number of Patients	0.80**
Number of RT-PCR Testing	0.69**
Number of Available Beds	0.67**
Number of Clusters	0.70**

*******p* **< 0.01**

Figure 1. Number of COVID-19 patients and RT-PCR testing per 100,000 population in each prefecture

Appendix Table 1. All variables in each prefecture.

Prefectures	Positive number	RT-PCR testing	Deaths	population (100,000)	Chinese visitors per 100,000	Physician per 100,000	Available beds for type 2 infection	Nurses per 100,000	Positive number per 100,000	RT-PCR testing per 100,000	Cluster infection	US Force Japan facility
Hokkaido	194	2445	9	53	16,696	243.1	92	1,219.4	3.7	46.3	2	1
Aomori	11	233	0	13	1,926	203.3	28	1,033.1	0.9	18.4	0	4
Iwate	0	86	0	12	299	201.7	36	1,098.9	0.0	6.9	0	0
Miyagi	26	514	0	23	762	238.4	27	867.3	1.1	22.2	1	0
Akita	11	419	0	10	733	234.0	30	1,153.0	1.1	42.7	0	0
Yamagata	13	434	0	11	501	226.0	16	1,076.2	1.2	39.8	0	0
Fukushima	16	328	0	19	402	204.9	34	920.7	0.9	17.6	0	0
Ibaraki	71	1806	2	29	478	187.5	46	765.5	2.5	62.8	2	0
Tochigi	14	759	0	19	1,685	226.1	30	846.8	0.7	39.0	0	0
Gunma	26	1361	1	20	492	228.3	50	974.5	1.3	69.7	2	0
Saitama	195	1647	4	73	449	169.8	66	693.6	2.7	22.5	0	3

Chiba	253	1297	1	63	5,658	194.1	55	722.7	4.0	20.7	2	1
Tokyo	1,123	4422	16	138	18,332	307.5	106	792.3	8.1	32.0	4	6
Kanagawa	261	1799	6	92	5,946	212.4	72	738.4	2.8	19.6	2	11
Niigata	32	1345	0	22	765	197.9	34	1,010.8	1.4	59.9	1	0
Toyama	11	381	0	11	2,958	254.4	20	1,211.1	1.0	36.3	0	0
Ishikawa	45	384	0	11	2,296	284.1	18	1,278.7	3.9	33.6	0	0
Fukui	57	335	2	8	1,072	252.6	18	1,161.8	7.4	43.3	0	0
Yamanashi	14	749	0	8	46,852	239.2	28	1,006.5	1.7	91.7	0	0
Nagano	14	736	0	21	2,781	233.1	44	1,083.3	0.7	35.7	0	0
Gifu	51	966	1	20	4,024	215.1	28	848.8	2.6	48.4	1	0
Shizuoka	10	1203	0	37	15,453	210.2	46	900.1	0.3	32.9	0	2
Aichi	237	3236	21	75	7,430	212.9	68	814.5	3.1	42.9	2	0
Mie	13	759	0	18	1,360	223.4	22	945.3	0.7	42.4	0	0
Shiga	18	334	0	14	980	227.6	32	999.0	1.3	23.7	0	0
Kyoto	119	1472	0	26	63,231	323.3	36	1,089.8	4.6	56.8	1	1
Osaka	429	1751	3	88	21,039	277.0	72	942.0	4.9	19.9	1	0
Hyogo	201	3054	12	55	2,750	252.2	46	996.7	3.7	55.7	4	0

Nara	26	374	0	13	39,029	258.5	22	964.7	1.9	27.9	0	0
Wakayama	27	1642	1	9	2,900	302.1	30	1,154.5	2.9	175.6	0	0
Tottori	0	242	0	6	1,185	304.8	10	1,282.1	0.0	43.2	0	0
Shimane	0	166	0	7	553	286.3	28	1,289.6	0.0	24.4	0	0
Okayama	11	479	0	19	1,147	308.2	24	1,239.4	0.6	25.2	0	0
Hiroshima	16	1348	0	28	966	258.6	28	1,102.1	0.6	47.9	0	5
Yamaguchi	12	449	0	14	517	252.9	38	1,263.6	0.9	32.8	0	2
Tokushima	3	174	0	7	1,186	329.5	21	1,235.2	0.4	23.6	0	0
Kagawa	2	371	0	10	3,006	282.5	22	1,195.5	0.2	38.6	0	0
Ehime	14	407	1	14	698	269.2	26	1,245.5	1.0	30.1	0	0
Kochi	34	565	0	7	944	316.9	9	1,511.0	4.8	80.0	0	0
Fukuoka	113	2415	0	51	2,655	302.6	64	1,189.2	2.2	47.3	0	1
Saga	8	223	0	8	2,771	280.0	22	1,335.4	1.0	27.2	0	0
Nagasaki	9	665	0	13	3,398	306.3	36	1,319.2	0.7	49.6	0	10
Kumamoto	20	1420	0	18	2,826	289.8	46	1,309.7	1.1	80.8	0	0
Oita	32	1843	0	11	8,164	275.2	38	1,276.2	2.8	161.1	1	0
Miyazaki	7	425	0	11	760	246.6	30	1,298.1	0.6	39.3	0	0

Kagoshima	3	414	0	16	1,588	270.8	44	1,394.3	0.2	25.7	0	0
Okinawa	15	480	0	14	44,865	240.7	20	1,060.6	1.0	33.1	0	31
Total	3817	48357	80	1264			1758		3.0	38.2	26	78

Appendix Table 2. Demographic characteristics of each variable

	Variables	Median (interquartile range [IQR])
1	Death*	0 (0-1)
2	Positives **	16 (11-54)
3	Number of RT-PCR testing**	665 (382.5-1446)
4	Available beds for type 2 infection	30 (23-46)
5	Population (100,000)	16.14 (10.86-27.04)
6	Number of physicians per 100,000 population	252.2 (224.7-283.3)
7	Number of nurses per 100,000 population	1089.8 (943.65-1242.45)
8	Chinese visitors to Japan per 100,000 population	1925.7 (763.4-4840.7)
9	Number of positives per 100,000 population*	1.138 (0.70-2.82)
10	Number of RT-PCR testing per 100,000 population*	38.6 (25.4-48.1)
11	Number of US Force Japan facilities	0 (0-1)
12	Number of clusters	0 (0-1)

* Number of cases reported by prefecture in Japan (as of 12:00 on March 15, 2020). Excluding charter flights and cruise ship patients.

** Number of new coronavirus-positive persons and number of persons performing PCR testing (does this mean lab technicians, i.e. people running the tests?) (by prefecture) (published on March 15, 2020). This is excluding those returning from charter flights.

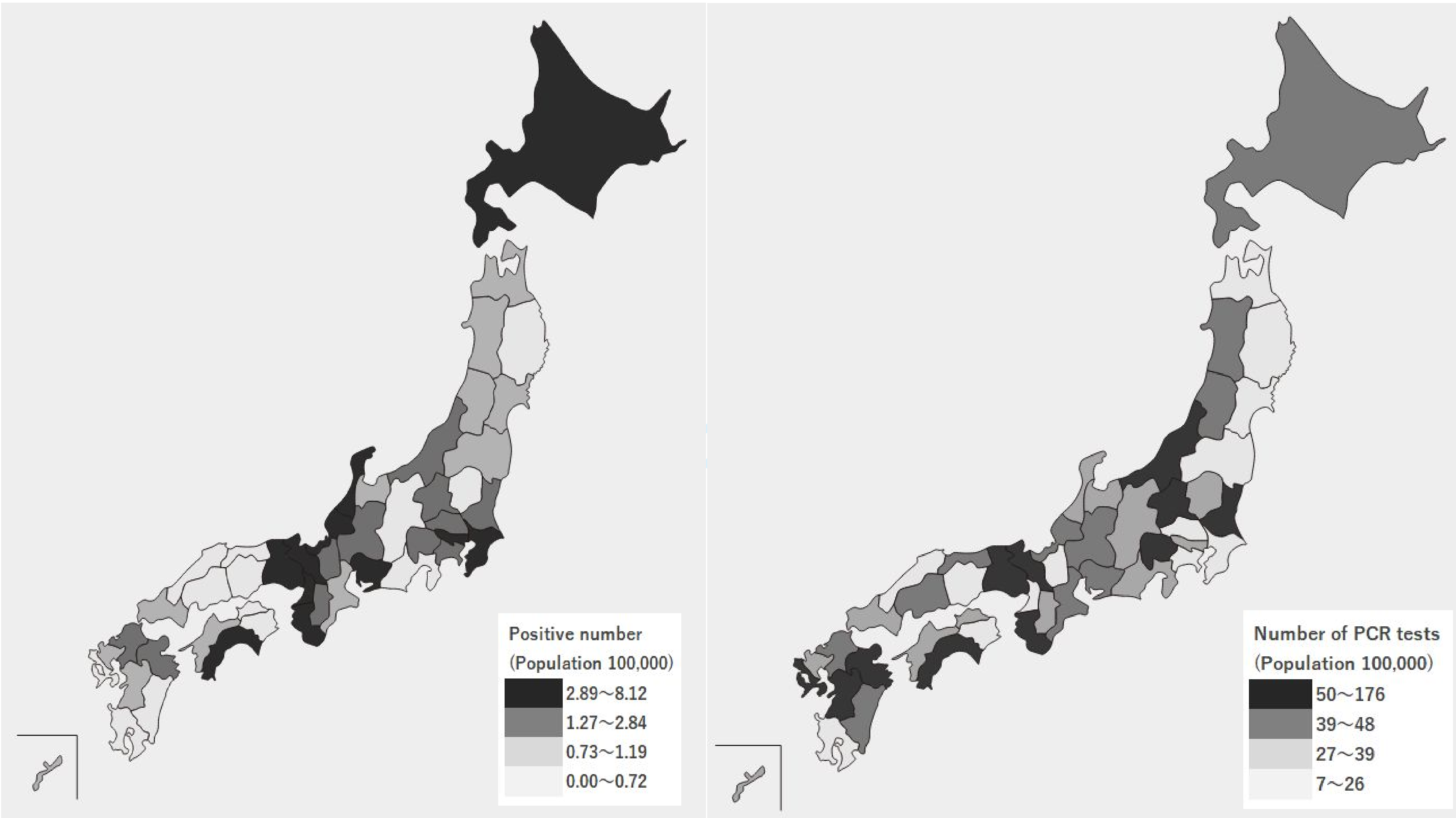
Positive number
(Population 100,000)
2.89～8.12
1.27～2.84
0.73～1.19
0.00～0.72
Number of PCR tests
(Population 100,000)
50～176
39～48
27～39
7～26

Figure 1