Positive Rate Is Useful to Evaluate the Sufficiency of RT-PCR Test Availability for COVID-19

Sadao Suzuki

Department of Public Health, Nagoya City University Graduate School of Medical Sciences, Nagoya, 467-8601 JAPAN

Abstract: Several articles have reported that the low number of COVID-19 cases in Japan is attributed to the small number of diagnostic RT-PCR tests performed. The criticism is based on the low number of the tests performed, and they suspected there would be more potential cases in Japan. The use of pre-test probability among tested subjects is proposed in order to evaluate of the sufficiency of test availability instead of the number of the tests. The pre-test probability means the average probability, *i.e.*, 'suspicion level', of having coronavirus among the tested subject in a country. The higher pre-test probability is regarded as less sufficient opportunity of the tests, and the test availability could be evaluated by the pre-test probability. Thus, potential problems of underestimation of COVID-19 cases by insufficient amount of the test would be clear by using pre-test probability. The comparison of the pre-test probability could be replaced with that of the positive rate of the test because of the linear relationship between them under the assumption of common sensitivity and specificity. Japan shows the third lowest rate (8.6%), and is considered that the considerably sufficient number of the tests have been performed. In conclusion, the positive rate of the test as a surrogate index of the pre-test probability is useful to evaluate the sufficiency of test amount instead of the number of the tests performed. In present, the potential problem of underestimation by insufficient test availability would be less serious in Japan.

Keywords: COVID-19, RT-PCR test, pre-test probability, positive rate

Several articles have reported that the low number of coronavirus disease 2019 (COVID-19) cases in Japan is attributed to the small number of diagnostic RT-PCR tests performed. For example, Financial Times said “there is debate over whether the spread has slowed or there are simply not enough tests being done” [1], and Business Insider “Japan has a remarkably low number of coronavirus cases that experts worry may lead to a 'false sense of security'” .[2] The criticism to Japan is based on the low number of the tests performed, and they suspected there would be more unreported dark figure in Japan.

PRE-TEST PROBABILITY AND SUFFICIENCY OF THE TEST

In this short report, I would like to discuss how to judge the impact of the dark figure due to insufficient test amount. As Director-General of World Health Organization mentioned ‘Test, test, test. Test every suspected case’, the diagnostic RT-PCR tests should be performed among suspected cases.[3] In general, screening test should be done according to the pre-test probability, otherwise we cannot expect enough positive predictive value. Thus, the subjects of RT-PCR test are carefully decided using information on pre-test probability in every county.

In this context above, if the pre-test probability is higher in country A than in country B, the test is performed more sufficiently in country B, since individuals in country B have same opportunities to get tested for a lower pre-test probability. Thus, the higher pre-test probability could be regarded as less sufficient opportunity of the tests in a country. And therefore, potential problems of dark number, *i.e.*, underestimation of COVID-19 cases by insufficient amount of the test, could be compared by pre-test probability conceptually.

POSITIVE RATE AS A SURROGATE INDEX FOR PRE-TEST PROBABILITY

Table 1 shows the two by two table for the RT-PCR tests results and COVID-19 diagnosis. From data of the reported number of tested subjects (n) and the number of test-positive cases (m)[4], the pre-test probability (p) is calculated below, under the condition of the given sensitivity (η) and specificity (θ):

$$p = \frac{m}{n}\frac{1}{\eta + \theta - 1} - \frac{1-\theta}{\eta + \theta - 1}$$

Since, $\eta pn + (1-\theta)(p-1)n = m$ (from Table 1)

Since the RT-PCR tests is used for diagnosis, the sum of sensitivity and specificity must exceed 1, the specificity is always less than 1, and m/n means the positive rate of the test, the equation above could be expressed by the following form:

$$p = a\,(\text{positive rate of the test}) - b,\ \text{where } a, b > 0$$

Therefore, the comparison of the pre-test probability could be replaced with that of the positive rate of the test because of the linear relationship between them under the assumption of common sensitivity and specificity.

The number of the RT-PCR tests, or even test rate among population, does not contain any information on disease distribution, and therefore, it is inappropriate to discuss the test availability or dark number based on it. The positive rate would be an index of RT-PCR test availability under the consumption of the common sensitivity and specificity. The assumption could be acceptable because RT-PCR test is performed under the standard manner, thus the test accuracy should not be so different as long as the background of the countries differ so much. At least, it is useful to know the positive rates are proportional to the pre-test probabilities under the consumption of the common sensitivity and specificity. The positive rate could be used not only for the comparison among countries but also for the time trend and area difference of the test availability within the country.

Table 2 shows the newest data in the number of the tested and test-positive cases, with the positive rate among selected seven countries, five countries of highest total cases (1st: United States, 3rd: Italy, 4th: France, 5th: Germany, and 6th: United Kingdom), South Korea and Japan. Spain, the second highest country, does not provide the COVID-19 testing statistics. South Korea shows the lowest positive rate (2.0%), in contrast, the U.K. shows the highest positive rate (31.8%). Japan shows the considerably low rate (8.6%). Thus, in present, the potential problem of underestimation by insufficient amount of the tests is more serious in U.K., France and the U.S. having the high positive rates, not in Japan.

CONCLUSION

The positive rate of the test as a surrogate index of the pre-test probability is useful to evaluate the sufficiency of test availability under the assumption of the common sensitivity and specificity. In present, ‘dark number’, the potential problem of underestimation by insufficient test availability would be less serious in Japan because of the relatively low positive rate.

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Table 1 Two by two table for the RT-PCR tests results and COVID-19 diagnosis

PCR test	**COVID-19 (+)**	**COVID-19 (-)**	**Total number**
Test positive	$\eta\, p\, n$	$(1-\theta)\,(p-1)\, n$	m
Test negative	$(1-\eta)\, p\, n$	$\theta\,(p-1)\, n$	$n-m$
Total number	$p\, n$	$(p-1)\, n$	n

Table 2 Number of diagnostic RT-PCR tests performed, and positive number and rate among selected seven countries

Country	Date	Number of the test	Test-positive number	Positive rate
United States	17-Apr	3,552,257	686,914	19.3%
Italy	17-Apr	1,244,108	172,434	13.9%
France	12-Apr	365,589	89,142	24.4%
Germany	15-Apr	1,728,357	132,766	7.7%
United Kingdom	17-Apr	341,551	108,692	31.8%
South Korea	17-Apr	546,463	10,635	2.0%
Japan	17-Apr	106,372	9,167	8.6%