Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Journal of the Formosan Medical Association 120 (2021) 2042–2043

Available online at www.sciencedirect.com

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journal homepage: www.jfma-online.com

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Real world clinical performance of SARS-CoV-2 rapid antigen tests in suspected COVID-19 cases in Taiwan

Taiwan experienced its first large-scale outbreak of the SARS-CoV-2 infection at the beginning of May 2021.[1] With no prior community outbreaks, the capacity of reverse transcription polymerase chain reaction (RT-PCR) at the time was unable to accommodate the testing need from the rapid increase in number of cases. The Taipei City government soon faces the threat of inadequate disease control resulting from untimely quarantine measures, mainly due to delayed obtainment of the RT-PCR results, in some cases up to 1 week. The Taipei City government later adopted a new quarantine policy based on a single rapid antigen test instead of rapid antigen tests and the RT-PCR results for COVID-19. Experts have raised concerns about the potential inaccuracy of the rapid antigen test due to the lack of clinical performance data of various test kits, low COVID-19 prevalence in Taiwan, and the lack of experience of healthcare workers in performing the rapid antigen test, which might result in unreliable results.[2]

To address this concern, we evaluated the real-world performance of SARS-CoV-2 rapid antigen tests in suspected COVID-19 cases during the outbreak in Taiwan. We collected data from 61 patients from our COVID-19 screening station who received simultaneous rapid antigen and PCR tests between May 1 and June 30, 2021, in Wan Fang Hospital and compared the results of the two tests under the assumption that a positive PCR test result is considered a definitive diagnosis. The rapid antigen test used is the Vstrip® COVID-19 Antigen Rapid Test (Panion & BF Biotech Inc., Xizhi Dist., New Taipei City 22146 Taiwan), which is a rapid immunochromatographic assay that utilizes specific antibodies to detect nucleocapsid protein of SARS-CoV-2 virus in nasopharyngeal swab specimens. The results showed that rapid antigen testing had a test specificity of 98.2% and sensitivity of 83.3% (MedCalc ver.20.009, MedCalc. Software Ltd., Ostend, Belgium). Under a disease prevalence of 0.06%, positive predictive value (PPV) and negative predictive value (NPV) were 2.68% and 99.99% (Table 1).

The 99.99% NPV from our result suggested that it is indeed justifiable to regard the antigen test as a "rule-out" test. In the United States, Pray et al. have reported the COVID-19 rapid antigen test PPV and NPV rates of 33% and 98% in populations with a disease prevalence of 5.2%.[3] This is in concordance with the current quarantine management policies in Taiwan, which dictates that anyone testing positive by the rapid antigen test is to be quarantined until the PCR test proves otherwise, while those testing negative are free to return home. The use of rapid antigen testing as a "rule-out" test is carried out in many countries, and its role should be carefully determined based on the disease prevalence.[4] As exposure to COVID-19 will likely be unavoidable in the following daily medical practice, the need for a cost-effective testing method will be crucial. Under the condition of low disease prevalence, the rapid antigen test provides means to significantly save time and cost and facilitate prompt medical decision-making by rapidly identifying low-risk individuals.

Table 1 Performance of SARS-CoV-2 rapid antigen tests in suspected COVID-19 cases.

(N = 61)	PCR Positive	PCR Negative
Antigen Positive	5	1
Antigen Negative	1	54
	Value	95% CI
Sensitivity	83.33%	35.88% ~ 99.58%
Specificity	98.18%	90.28% ~ 99.95%
Positive Predictive Value	2.68%	0.38% ~ 16.55%
Negative Predictive Value	99.99%	99.4% ~ 100%
Disease Prevalence	0.06%	

https://doi.org/10.1016/j.jfma.2021.07.011

Declaration of competing interest

The authors have no conflicts of interest relevant to this article.

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2 July 2021