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10.2478/AMB-2023-0035

SHORT COMMUNICATION

HOW SENSITIVE AND SPECIFIC ARE RAPID ANTIGEN TESTS FOR SARS-COV-2 – THE EXPERIENCE OF ONE OF THE BIGGEST BULGARIAN HOSPITALS

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Abstract. *Rapid point-of-care tests that detect antigens specific for SARS-CoV-2 are less expensive and faster than the standard molecular methods. However, their accuracy varies widely between tests, populations and settings. We decided to assess the diagnostic precision of antigen tests for SARS-CoV-2 in a real-life hospital environment. In a cohort of 2677 hospitalized patients, we found a sensitivity of 60.2% (95% CI 57.1%-63.4%) and a specificity of 98.1% (95% CI 97.4%-98.7%) for the antigen tests when compared to RT-PCR. The accuracy of antigen testing could be acceptable in a hospital setting, especially when the result is consistent with the clinical and epidemiological context. When there is discordance between the antigen test result and the patient's symptoms, a confirmation with molecular methods is needed.*

Key words: *COVID-19, sensitivity, specificity, point-of-care systems*

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Received: *29 March 2023,* ***Accepted:*** *28 July 2023*

INTRODUCTION

In a matter of days after the first COVID-19 cases, sequencing and nucleic acid amplification tests, namely reverse transcription polymerase chain reaction (RT-PCR), were rapidly developed and implemented into clinical practice. These techniques became a gold standard for accurate SARS-CoV-2 detection but regularly generated a significant delay in diagnosis because of their time-consuming protocols. With the massive accumulation of infected people, the need for rapid conclusions has increased and led to the appearance of antigen immunoassays which could generate results in 15 minutes. Soon, they turned into the most preferred method of COVID-19 screening for health-related and other purposes. Hundreds of studies have evaluated their precision – in general, antigen assays are considered less sensitive and specific than molecular methods, and their accuracy depends on sampling, viral load or tested individuals [1]. Most of these studies were laboratory-based, and the overall accuracy of SARS-CoV-2 rapid tests in real-life hospital environment (parallel emergent and planned admissions; reached capacity; irregular availability of tests; diverse test suppliers; different staff training) is still not well defined. Therefore, we decided to assess the diagnostic precision of rapid antigen tests for SARS-CoV-2 and to see if they were sufficiently accurate to detect COVID-19 in hospitalized patients.

MATERIALS AND METHODS

For this study, we retrospectively analyzed the SARS-CoV-2 testing results obtained between

01.01.2021 and 31.12.2021 in a consecutive cohort of hospitalized patients in the University Hospital "Sv. Marina", Varna, Bulgaria. At admission (planned or urgent), all patients were tested for SARS-CoV-2 infection with a rapid antigen test. Patients with a negative result and without respiratory infection symptoms were not further tested. Positive patients, individuals with a negative result but with respiratory symptoms, and patients with a negative result but with a history of COVID-19 contacts were tested via multiplex RT-PCR in 24 hours after admission.

For both antigen and RT-PCR testing, naso-oropharyngeal swabs were collected from the patients. Antigen tests were performed at the admitting clinic or emergency department following the instructions of the manufacturer. Samples for PCR confirmation were transported to the virology laboratory in saline water or a viral transportation medium.

RNA extraction was performed with SaMag Viral Nucleic Acid Extraction Kit using SaMag-12 instrument (Sacace Biotechnologies, Italy) or Maccura Mag-Bind RNA Extraction Kit using Allsheng Auto-Pure 32A System (Maccura Biotechnology, China). Isolated RNAs were amplified with a SARS-CoV-2 Real-TM kit (Sacace Biotechnologies, Italy) following the standard manufacturer's instructions.

Sensitivity and specificity were calculated with MedCalc Software Ltd. (https://www.medcalc.org/calc/diagnostic_test.php, version 20.218) with the following formulas: Sensitivity = number of true positive cases/number of true positive cases + number of false negative cases; Specificity = number of true negative cases/number of true negative cases + number of false positive cases.

RESULTS

From January to December 2021, 2677 individuals (1362 males and 1315 females) were tested via the SARS-CoV-2 rapid antigen test and RT-PCR. Their age varied from 0 to 97 years.

Most patients (2068, 77.3%) had a negative antigen test for SARS-CoV-2. Positive rapid tests were 609 (22.7%). The confirmation RT-PCR produced 1719 negative (64.3%) and 958 (35.7%) positive results. A total of 413 patients (15.4%) had discordant COVID-19 tests – 381 individuals were antigen negative/PCR positive, and 32 were antigen positive/PCR negative. Antigen tests correctly identified COVID-19 infection in 60.2% (95% CI 57.1-63.4%) and ruled out infection in 98.1% (95% CI 97.4-98.7%) of the tested individuals. The overall accuracy of rapid testing was 84.6% (95% CI 83.2-85.9%).

DISCUSSION

We found a sensitivity of 60% and a specificity of 98% for the rapid SARS-CoV-2 tests used in a cohort of consecutive patients admitted to a tertiary hospital for a period of one year during the COVID-19 pandemic. The accuracy of antigen assays varies widely between studies, but the most recent Cochrane systemic review found similar sensitivity of 73% and 55% and specificity of 99.6% and 99.7% in symptomatic and asymptomatic individuals, respectively [2]. As our sample was of mixed patients (with and without symptoms), the results obtained were between those of symptomatic and asymptomatic patients.

A significant strength of the current study is its real-life and point-of-care character – the antigen testing was performed in a working hospital setting. So, the obtained data correspond to a high degree to the real situation. The study was not laboratory-based – it did not focus on only one rapid test (usually from one batch) but analyzed the overall accuracy of different antigen assays. From another point of view, this is also a limitation, as the accuracy might vary between manufacturers. In addition, information about the symptoms in many patients has been missing, and we could not compare sensitivity and specificity in symptomatic and asymptomatic individuals.

CONCLUSION

Antigen testing in our hospital meets the WHO minimum performance requirement of 97% for specificity but not for sensitivity (60% versus the required 80%) [3]. We could conclude that antigen tests have acceptable accuracy for urgent decisions in hospitals. However, when molecular methods are available, and there is a controversy between symptoms and test results, a new sample should be collected and retested with an RT-PCR assay.

Funding: *This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.*

Ethics: *The study was retrospective analysis of laboratory results. No sensitive data were retrieved and no patients' intervention was performed.*

Disclosure Summary: *The authors have nothing to disclose.*

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