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Evaluation of Rapid Antigen Test as A Screening Test for SARS-CoV-2 Infection Among Healthcare Workers

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Abstract

Background: COVID-19 disease first appeared in late 2019, then quickly became widespread and had an impact on all areas of the labor and economy, particularly the healthcare sector. Accurate rapid screening of healthcare workers for COVID-19 infection was mandatory during the pandemic. **Aim of work:** To validate the rapid antigen test as a screening test in comparison to the gold standard test (RT-PCR) at Cairo university hospitals (tertiary care hospitals) among healthcare workers in a field study. **Methods:** This study is a cross sectional study, that was conducted on healthcare workers from different groups (doctors, nurses, paramedical personnel, cleaning workers) at Kasr Al-Ainy COVID-19 worker's screening zone at the outpatient clinics, in Cairo, Egypt. From 25th march, 2021 to 30th October 2022. All the participants completed a questionnaire about their occupational history and exposures, infection control measures compliance, risk factors, clinical manifestation suspicious for COVID-19. A rapid antigen tests were done at COVID-19 for the 146 participants of healthcare workers, then the samples were sent to the lab to perform RT-PCR at the same day. The nasopharyngeal samples were collected from highly suspicious symptomatic ± close contacts to positive patient or a co-worker. The study group was later subdivided according to the PCR results (the standard test) to PCR positive group which included 87 positive COVID-19 healthcare workers, and PCR negative group included 59 COVID-19 negative healthcare workers. **Results:** It was found that RAT sensitivity equals 62.07%, RAT specificity equals 100 %, RAT positive predictive value (the ability of the test to predict positive cases) was 100 %, RAT negative predictive value (the ability of the test to predict negative cases) was 64.13% and RAT accuracy was 77.4 %. **Conclusion:** Rapid antigen testing using nasopharyngeal swabs can be performed as a screening test for suspicious healthcare workers despite lower sensitivity than the gold standard test (PCR).

Key words: COVID-19, Healthcare, Screening, Rapid Antigen Test

Introduction:

On December 31st, 2019, the World Health Organization (WHO) China Country Office received notification of pneumonia patients with unclear etiology in Wuhan City, Hubei Province, China. On January 7th, 2020, following virus isolation, Chinese authorities determined the cause of these pneumonia cases to be a new form of coronavirus belonging to the genus β. The World Health Organization named the virus "The novel severe acute respiratory syndrome corona virus-2" (SARS-CoV-2) and named the disease by" Coronavirus Disease of 2019 (COVID-19 (at the beginning of 2020 year, on 11th Mar 2020, WHO declared (COVID-19) as a pandemic (1&2).

The healthcare workers are inevitable close contact with patients who are infected with SARS-CoV-2, so they are at high risk of infection, that affects their health and contributing to more spreading of infection (3). The accurate rapid diagnosis of COVID-19 infection among healthcare workers (HCWs) is an important step in severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) transmission control in healthcare setting. Viral detection tests are recommended for diagnosis of acute infection in both symptomatic and asymptomatic individuals (especially HCWs), to guide treatment options, contact tracing, and quarantine or isolation requirements (4).

Nucleic acid amplification tests (NAATs) like RT-PCR (reverse transcription polymerase chain reaction) are the gold standards in the diagnosis of SARS-CoV-2 infection. Unfortunately, they take long hours of samples preparation, moreover, they need experience to be performed (5). Rapid antigen tests (RATs) are frequently used to diagnose respiratory infections. Antigen tests are immunoassays that detect the presence of a specific viral antigen, indicating that a virus is currently causing infection. RATs have many advantages, e.g. they are relatively inexpensive and can be used at the point-of-care. The currently authorized kits return results in approximately 15 minutes (6). However, the accuracy of antigen detection tests, compared with that of NAATs, is an area of interest for the rapid diagnosis of SARS-CoV-2 infection (7).

Aim of work:

To validate the rapid antigen test as a screening test in comparison to the gold standard test (RT-PCR) at Cairo university hospitals (tertiary care hospitals) among healthcare workers in a field study.

Methods:

This study design is a cross sectional study, that was conducted on healthcare workers from different groups (doctors, nurses, paramedical personnel, cleaning workers) at Kasr Al-Ainy outpatient clinic, in Cairo, Egypt. Approval was got from the institutional review board (IRB). Any healthcare worker who reported symptoms strongly suggesting SARS-CoV-2 infection, male or female, doctor, nurse, paramedical personnel and environmental service providers (cleaning and housekeeping workers) were included in the study. Any healthcare worker who refused to participate in the study, other workers who were not healthcare

workers as the screening clinic provide the test for university employee other than healthcare workers and those who had no symptoms or history of close contact with infected case but performed the PCR for another purpose, were excluded. From 25th march, 2021 to 30th October 2022, 146 nasopharyngeal samples were collected from highly suspicious symptomatic ± close contacts to positive patient or a co-worker. The study group was later subdivided according to the PCR results (the gold standard test) to PCR positive group which included 87 positive COVID-19 healthcare workers, and PCR negative group included 59 COVID-19 healthcare workers. All the participants completed a questionnaire about occupational history and exposure, infection control measures compliance, risk factors, clinical manifestation suspicious for COVID-19. A rapid antigen tests were done at COVID-19 screening clinic, then the samples were sent to the lab to perform RT-PCR at the same day.

Statistics/data analysis:

Sample size was calculated as minimum number of diseases needed: 73 subjects and minimum total sample size needed: 146 subjects, the source of sample size is calculator program version 3.0.43.it was based on the following inputs: power of 80 % significance with level of 0.05 alpha error. Data were coded and entered using the statistical package for the Social Sciences (SPSS) version 28 (IBM Corp., Armonk, NY, USA). Data was summarized using mean, standard deviation, median, minimum and maximum in quantitative data and using frequency (count) and relative frequency (percentage) for categorical data. Comparisons between quantitative variables were done using the non-parametric Mann-Whitney test. For comparing categorical data, Chi square (X2) test was performed. Exact test was used instead when the expected frequency is less than 5. Standard diagnostic indices including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic efficacy were calculated. P-values less than 0.05 were considered as statistically significant.

Results:

Table (1) demonstrates the positive and negative results of the RT-PCR test which is the gold standard test, and the RAT among the participants. Table (2) demonstrates that performance of RAT in comparison to the standard test (PCR), It was found that RAT sensitivity equals 62.07%, RAT specificity equals 100 %, RAT positive predictive value (the ability of the test to predict positive cases) was 100 %, RAT negative predictive value (the ability of the test to predict negative cases) was 64.13% and RAT accuracy was 77.4 %. Table (3) demonstrates the most common side effects that the participants reported it immediately after performing nasopharyngeal swab like bleeding from nose (5.5 % of the participants), nasal discomfort (52.4% of the participants), Headache (13.8%), Ear discomfort (5.5%), Rhinorrhea (22.8%). Table (4) demonstrates that there is no significant statistical difference regarding to the prevalence of presence of side effects of nasopharyngeal swabbing procedure between COVID-19 positive and COVID-19 negative participant.

Tables:

Table (1) Results of polymerase chain reaction (PCR) test, and rapid antigen test (RAT).

Table (2) Two by two table to calculate the sensitivity, specificity, negative predictive value and positive predictive value of rapid antigen test(RAT), in comparison to PCR (the standard test).

		PCR			
		Positive		Negative	
		No	%	No	%
RAT	Positive	54	62.1%	0	0.0%
	Negative	33	37.9%	59	100.0%

		No.	%
PCR	Positive	87	59.6%
	Negative	59	40.4%
RAT	Positive	54	37.0%
	Negative	92	63.0%

Statistic	Value	95% CI
Sensitivity	62.07%	51.03% to 72.26%
Specificity	100.00%	93.94% to 100.00%
Positive Predictive Value	100.00%	93.40% to 100.00%
Negative Predictive Value	64.13%	57.74% to 70.05%
Accuracy	77.40%	69.75% to 83.90%

Table (3) The prevalence of short-term complication after the nasopharyngeal swabbing procedure among all the study population.

		No	%
Epistaxis	Yes	8	5.5%
	No	138	94.5%
Nasal discomfort	Yes	77	52.7%
	No	69	47.3%
Headache	Yes	20	13.7%
	No	126	86.3%
Ear discomfort	Yes	8	5.5%
	No	138	94.5%
Rhinorrhea	Yes	33	22.6%
	No	113	77.4%

Table (4) comparison of the prevalence of short-term complication of nasopharyngeal swabbing procedure between COVID-19 positive and negative population.

		PCR				P value
		Positive		Negative		
		No	%	No	%	
Epistaxis	**Yes**	5	5.7%	3	5.1%	1
	No	82	94.3%	56	94.9%	
Nasal discomfort	**Yes**	45	51.7%	32	54.2%	0.765
	No	42	48.3%	27	45.8%	
Headache	**Yes**	15	17.2%	5	8.5%	0.131
	No	72	82.8%	54	91.5%	
Ear discomfort	**Yes**	5	5.7%	3	5.1%	1
	No	82	94.3%	56	94.9%	
Rhinorrhea	**Yes**	18	20.7%	15	25.4%	0.502
	No	69	79.3%	44	74.6%	

Discussion:

The effects of COVID- 2019 pandemic permeated all aspects of society globally. One of the pandemic large effects was the great influence on the global workforce in general, which is multifaceted and complex, warranting careful reflection and consideration to mitigate the adverse effects on workers worldwide, and increased the awareness of the pandemic risk impact on healthcare workers in particular (8).

Many diagnostic test manufacturers were actively involved in the design, development, validation, verification, and implementation of diagnostic tests during the early stages of the coronavirus disease 2019 (COVID-19) pandemic. There has been a rapid development of hundreds of molecular diagnostics and immunoassays. Also, several diagnostic rapid antigen tests were still waiting for formal endorsement and clinical validation (9). The goal of this study was to validate the commercially available rapid antigen test as a screening test, in comparison to RT-PCR, and if it is possible to depend on it in screening of healthcare workers for detection of infected personnel.

The sensitivity and specificity of rapid antigen test were calculated in this study in comparison to RT-PCR test (the gold standard test) that is used globally to diagnose COVID-19 infection. It was found that the sensitivity of the test in this study equals 62.07%, specificity was found to equal 100%, positive predictive value that equals 100%, negative predictive value equals 64.13%, and the test accuracy was found to equal 70.4%.

In accordance with this study results, the study held by Jegerlehner et al., (2021) found that among 1465 patients who attended for being screened for SARS-CoV-2 infection at a COVID-19 testing facility affiliated to a Swiss University hospital were recruited for the study, RT-PCR test was positive in 141(9.6%) subject of them, the rapid antigen test was positive in 94 patients (6.4%), and negative in 1368 subjects, and found that the overall sensitivity of the rapid antigen test was 65.3%, the specificity was 99.9%, and concluded that

widespread application of rapid antigen test in a setting of primary/secondary care setting might lead to a considerable number of individuals falsely classified as SARS-CoV-2 negative (10).

Another similar study conducted by Iglỏi et al., (2021) at the largest drive-through testing location in Rotterdam-Rijnmond, for screening test included either presence of symptoms or close contact with a confirmed SARS-CoV-2–infected person, and used the SD Biosensor SARS-CoV-2 rapid antigen test (the test which was used in the current study) against RT-PCR results found that the overall test sensitivity was 84.9% (higher sensitivity than this study) and specificity was 99.5%. also, it was found that sensitivity increased to 95.8% for persons who sought care within 7 days of symptom onset (11).

Also in accordance to the current study, a cross-sectional community-based diagnostic accuracy study was conducted by Sania et al., (2022) to evaluate the diagnostic performance and feasibility of rapid antigen testing for SARS-CoV-2 detection in low-income communities. It was found that the sensitivity of rapid antigen tests was 68 %, and specificity was 98% using the nasal samples. The previously mentioned study also explained that when the goal of testing is to mitigate transmission, the ideal test would be one that not just identifies the presence of SARS-CoV-2 but identifies those individuals that contribute to virus transmission. Therefore, despite lower Sensitivity of rapid antigen tests compared with the gold standard (PCR), and because of the immediacy of their results, as well as their low cost and ease of administration, rapid antigen tests are an ideal method for use in the screening. (12).

In the present study questionnaire, the participants were asked if they developed number of symptoms shortly after nasopharyngeal swabbing as adverse effects of this procedure, and it was found that the most common complaint was nasal discomfort 52.7%, followed by rhinorrhea 22.6 %, headache 13.7%, both ear discomfort and epistaxis were about 5.5%. When comparing between the participants who tested positive or negative for SARS-CoV-2, no statistically significant difference was detected as regards the prevalence of these symptoms.

In a similar study held in otorhinolaryngology emergency department of Helsinki University Hospital by Koskinen, et al., (2021) about complications of COVID-19. nasopharyngeal swab test, during the 7-month study period, only Eight subjects with complication were reported in the total 2899 otorhinolaryngology ED tested patients, 4 of them were epistaxis that occurred immediately after sampling, the other 4 were broken swabs (13).

A systematic review made by Kim, et al., (2022) about complications of nasopharyngeal swabs and safe procedures for COVID-19 Testing Based on Anatomical Knowledge, it was found that A total of 27 articles were selected for the review of 842 related documents in PubMed, Embase, and KoreaMed. The complications secondary to nasopharyngeal COVID-19 testing were reported to be rarely occurred, ranging from 0.0012 to 0.026%. Frequently documented adverse events were retained swabs, epistaxis, and cerebrospinal fluid leakage,

often associated with high-risk factors, including severe septal deviations, pre-existing skull base defects, and previous sinus or trans-sphenoidal pituitary surgery. None of these adverse effects were reported in the current study (14).

Conclusion and recommendations:

It is concluded that rapid antigen test using nasopharyngeal swabs can be performed as a screening test for suspicious healthcare workers despite lower sensitivity than the gold standard test (PCR), as it aids to do rapid testing for healthcare workers in low-resource settings. it is an inexpensive method that can increase testing capacity, accessibility and the effectiveness of infection control measures depending on immediately obtained results. This study recommends doing further studies on large scale for improvement of commercially available rapid antigen tests to increase their sensitivity. Also, further studies must be done on other methods of specimen collection other than nasopharyngeal swabbing that caused annoying side effects for number of participants.

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Conflicts of interest: The authors affirm that they have no conflicts of interest.

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