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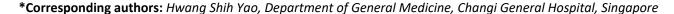
Infectious Diseases and Epidemiology

BRIEF REPORT

Self-Swab and Saliva Collection for the Diagnosis of Covid-19. What Do Patients Feel About Them?

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Abstract

Purpose: Self-collected oropharyngeal, nasal mid-turbinate (OPMT) swabs, are being evaluated as diagnostic tools for COVID-19.

Methods: The study was conducted on 100 healthy volunteers. The participants did a self-swab, healthcare worker collected swab, and collected saliva after an instructional video. A user preference survey was conducted thereafter.

Results: Most subjects were confident in performing the tests. More participants found it easier to self-swab. There is no clear preference for the self-collection method.

Conclusion: The false-positive rate for self-collection methods is low. These tests can be deployed to various scenarios, depending on the test cohort and intent of testing.

Keywords

Self-swab, Saliva, COVID-19, Diagnosis

Introduction

SARS-CoV-2 is the virus being detected for tests for the illness COVID-19. The current gold standard for diagnosis of COVID-19 is a healthcare worker (HCW) performed nasopharyngeal (NP) swab. The IDSA (Infectious Diseases Society of America) suggests using nasopharyngeal, mid-turbinate, or nasal specimens rather than an oropharyngeal (or saliva) specimen because of limited data suggesting lower sensitivity with oropharyngeal specimens. However, subsequent studies have suggested that saliva specimens compare favorably with nasal specimens, and in the United States, several

saliva-based assays have received emergency use authorization. Self-collected samples have also started to receive attention, as it can allow increased testing capacity, and it could reduce the infectious exposure to healthcare workers, and aid in efforts to conserve personal protective equipment (PPE). Initial studies done to compare the effectiveness between HCW performed NP swabs and self-collected saliva samples show that positivity rates for saliva samples are similar to those of NP samples [1]. Another study showed that self-collected saliva samples had a higher detection rate compared to HCW NP swabs (90% vs. 85%) [2]. There have also been studies done in the Singapore population that show that saliva testing is a sensitive and less intrusive method of COVID-19 testing [3]. There is however no prior study on user preferences and feedback when it comes to the various self-collection methods.

Methods

We conducted this study with 100 healthy volunteers using two different testing methods - the bilateral nasal mid turbinate and throat swab, as well as the deep throat saliva sample. The 100 subjects were well and did not have any symptoms of an acute respiratory tract infection. These subjects also did not have any exposure to persons confirmed to have COVID-19 and did not work in areas with a high prevalence of COVID-19.

All participants watched a useful instructional video for both testing methods then performed a self-swab



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before getting an HCW performed swab, also of the bilateral nasal mid turbinate and throat. They then collected the saliva sample. A user preference survey is then conducted after this process.

Synthetic fiber swabs were used for the collection of oropharyngeal and mid-turbinate samples by both subject and healthcare worker, while SAFER-Sample™ (by Lucence Diagnostics) was used to collect saliva samples. The swab kit contained a swab stick, a sample tube with Universal Transport Media (UTM). Hand-held mirrors were provided, and a separate cup was given to hold the UTM tube in place. The saliva collection kit contains a collection instruction sheet and a clamshell box. The clamshell box contained, a saliva collection funnel, a sample tube containing stabilizing liquid, and a blue cap.

Samples were transferred to the lab on the same day for RT-PCR testing. The test results (detected/non-detected and the corresponding Ct values) were transmitted by an excel spreadsheet from the lab to investigators for analysis. The extraction process is carried out using the PerkinElmer Nucleic Acid Extraction Kits (KN0212) and run on the Quantstudio 5 Real-Time PCR System using the PreNat II Automated RNA Extraction Kits. Extraction of swab samples followed the indicated protocol for oropharyngeal swabs, while the extraction of saliva samples followed a provisional protocol that was crafted by PerkinElmer in discussion with the manufacturer.

Results

There were a total of 100 participants, age range between 22 and 70-years-old. The age group with the most subjects comprised of those between age 31 and 40 (36%). There were 51 women, and 49 men that were enrolled in the study. All swabs were tested negative (negative correctness 100% 95% CI 96.4% to 100% with an error rate of 3.6% on having no false negatives).

The study team observed that 6 subjects experienced difficulties in doing the self-swab, with fear and apprehension of swabbing themselves cited as the main reason. As a result, they did a fairly shallow swab. One subject was not sure how to remove the swab stick from the kit; one had difficulty breaking the swab stick, and one needed frequent prompting despite the video instruction and a pictorial guide.

Table 1 illustrates the breakdown of responses to the questions that were presented to the user preference survey.

For the self-swab component, all subjects mentioned that video instruction was easy to follow. 84% of participants were confident in performing the self-swab. Based on their experience with the self-swab alone, 88% would choose to perform a self-swab if given a choice between doing a self-swab and an HCW perform the swab for them. The majority (99%) felt that the

swab kit was user-friendly. The one subject that found the swab kit not user-friendly needed an additional cup to be provided to hold the sample tube steady.

For the saliva sample component, 71% of participants found it easy to provide a saliva sample, and 89% would choose to provide a saliva sample if given a choice as opposed to an HCW swab. All but one subject found the video instructions easy to follow.

When given choice between the 2 self-collection methods, it was an equal divide between the self-swab and saliva, at 38% each. 24% of the subjects did not have a preference.

Discussion

Based on the results of this study, the overall impression shows that participants had more confidence in doing saliva sample collection as opposed to the nose and throat swab.

The subjects were also able to provide qualitative feedback on their experience. When it comes to the self-swab, the participants were mainly uncertain about how far to put the swab in, and they found it useful to have an HCW guiding this process. They also men-

Table 1: Summary of responses to user preference survey.

| Self-swab | n (%) |
|---------------------------------------|-----------|
| Confidence in performing self-swab | |
| Very fearful | 1 (1.0) |
| Fearful | 15 (15.0) |
| Confident | 67 (67.0) |
| Very confident | 17 (17.0) |
| Choose self-swab over HCW swab | |
| Definitely not | 3 (3.0) |
| Will not | 9 (9.0) |
| Will | 51 (51.0) |
| Definitely will | 37 (37.0) |
| Saliva Sample | |
| Difficulty providing saliva sample | |
| Very difficult | 2 (2.0) |
| Difficult | 27 (27.0) |
| Easy | 52 (52.0) |
| Very Easy | 19 (19.0) |
| Choose saliva testing | |
| Definitely not | 0 (0.0) |
| Will not | 11 (11.0) |
| Will | 50 (50.0) |
| Definitely will | 39 (39.0) |
| Overall | |
| Preferred method of sample collection | |
| No preference | 24 (24.0) |
| Saliva collection | 38 (38.0) |
| Self-swab | 38 (38.0) |

tioned that the HCW swab felt more thorough and went in deeper as compared to their self-swab. A suggested improvement was to put a marking on the swab stick to guide how deep to go. The performance of the self-swab is also prone to inconsistencies, which can be influenced by the personal motivation of the person undergoing the test.

For the saliva sample component, there was general difficulty in generating saliva and there was uncertainty as to when enough saliva is collected. This particular test kit required the collection of 2 ml of saliva, which posed a challenge for some. Participants feel that it requires more time to collect saliva and there was also uncertainty if fluid collected is truly oropharyngeal sputum. There was also difficulty in the collecting apparatus of the saliva sample as the flow of saliva from the funnel to the test receptacle might be slow given the viscosity of the sample. A suggested improvement is to reduce the amount of saliva required for testing.

The added step of adding the stabilizing fluid was also prone to mishaps, where some subjects had to be reminded on this step, some were not sure if the funnel was to be removed before pouring the stabilising fluid.

Both the self-swab and saliva collection require a level of dexterity, and this would reduce its applicability in the group who are unable to follow the steps. While the saliva collection process is a very attractive option for COVID-19 testing, as there is minimal discomfort to the person undergoing the test, the collection process ought to be simplified to minimize the risk of error.

Based on the user feedback on both the self-collection methods, it would seem that the self-swab is more suitable to be carried out in a highly motivated population; one example would be persons working in an environment with high-risk infectious exposure. The saliva-testing performance is likely more consistent, and less prone to differences in dexterity and test motivation.

Conclusion

This study shows that the negative correctness for both self-swab and saliva testing is 100% in this study population. There are still improvements to be made with regards to self-collection methods for the nasal and throat swab as well as the saliva sample. It is also important to choose the right testing method in each respective clinical setting. With increasing confidence and data for these self-collection methods for testing of COVID-19, there will be a lesser need for unnecessary exposure for HCW or swabbers in the future.

Declarations

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