Validation of saliva specimen over nasopharyngeal swab for Coronavirus Disease 2019 amidst shortage of swabs in a tertiary hospital

Theresa Vu MD, Shazia Afreen MD, Melissa Lara MD, Jeremy Adrian MS3, Juan Chiriboga MD
Family Medicine Residency Program - San Joaquin General Hospital

Introduction

- The Coronavirus Disease 2019 (COVID-19) pandemic was marked by increasing demand for rapid diagnostic testing as infection spread across the United States (U.S.)[1].
- The gold standard test for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) diagnosis is real-time reverse transcriptase (RT-PCR); the predominant specimen used is nasopharyngeal (NP) swab[2].
- The NP sample has several limitations: shortages of testing material, risk of exposure of healthcare professionals, requirement of personal protective equipment, and patient discomfort.
- Our objective is to add to the growing body of evidence that saliva based (SB) testing can be used as an accurate and reliable sample in place of NP swab for detection of SARS-CoV-2 by RT-PCR

Methods

Study design: Prospective cohort study

Setting: Drive-through COVID-19 testing site

Population: 100 participants aged 17-83, mean age 42.8

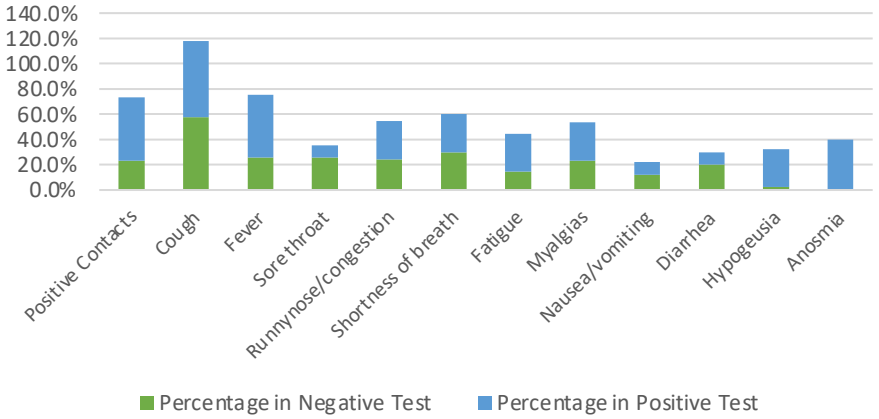
Inclusion criteria: Patients >13 years of age who were either symptomatic or had confirmed exposure to a COVID-19 patient

Exclusion criteria: Patients who were asymptomatic, pregnant, hospitalized, or homeless

All patients were tested with both NP swab and saliva test. NP swab was performed by healthcare professional while saliva specimens were self-collected into a sterile urine cup.

Results

Percentage of Patients Reporting Symptoms in Negative or Positive Test



Comparison between saliva and NP testing

	NP		
Saliva	Positive	Negative	Total
Positive	6	3	9
Negative	1	90	91
Total	7	93	100

- Saliva-based testing when compared to NP swabs:
- Sensitivity: 85.7% (95% CI 42.13%-99.64%)
- Specificity: 96.8% (95% CI 90.86%-99.33%)
- PPV: 66.67% (95% CI 38.69%-86.37%)
- NPV: 98.90% (95% CI 93.61%-99.82%)
- Overall concordance rate: 96.0%
- Cohen's kappa coefficient: 0.7286 (95% CI, 0.468-0.989)
- Sensitivity when compared to any positive test:
  - Saliva-based: 90% (95% CI 55.5%-99.7%)
  - Nasopharyngeal: 70% (95% CI 34.7%-99.3%)

Discussion

- In the midst of a national shortage of supplies, using saliva as a specimen is pivotal in order to achieve large-scale and repeated testing for detection of SARS-CoV-2.
- In our study, the strong concordance rate between both types of samples indicates that the use of saliva is as reliable as NP swab testing.
- Saliva collection is non-invasive and does not require trained healthcare personnel to collect the sample.
- Limitations:
  1) In the absence of a true diagnostic gold standard, it is difficult to ascertain definitive sensitivities and specificities. In our study, 20% of total positive results were detected by saliva alone. This is suggestive of possible false-negatives with NP swabs. This further corroborates that NP swabs may be unreliable as a gold standard.
  2) An increased sample size would have provided a more accurate sensitivity calculation and lowered the confidence intervals. This data alone is not enough to make a compelling case for saliva testing.

Conclusion

- SB testing can increase patient compliance due to lack of discomfort and ability to self-administer and drop-off results for sample collection.
- The detection of SARS-CoV-2 through saliva specimens will protect healthcare workers, reduce staffing needs, and minimize PPE waste. This in turn reduces costs associated with testing.
- This study encourages the use of saliva-based testing for the laboratory diagnosis of COVID-19. However, the present study highlights the importance of testing larger samples of participants in order to promote saliva to an established alternative to nasopharyngeal swab testing.

References

1. COVID-19: Testing Demand Keeps Lab Fellow on the Go. Centers for Disease Control and Prevention. Updated July 22, 2020. Accessed October 30, 2020. https://www.cdc.gov/coronavirus/2019-ncov/communication/responder-stories/testing-demand.html.
2. COVID-19: Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing. Centers for Disease Control and Prevention. Updated February 26, 2021. Accessed November 10, 2020. https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fguidelines-clinical-specimens.html.