ORAL SALIVA SWAB RT-PCR AS A FIT FOR-PURPOSE DIAGNOSTIC TEST FOR COVID-19 IN CHILDREN

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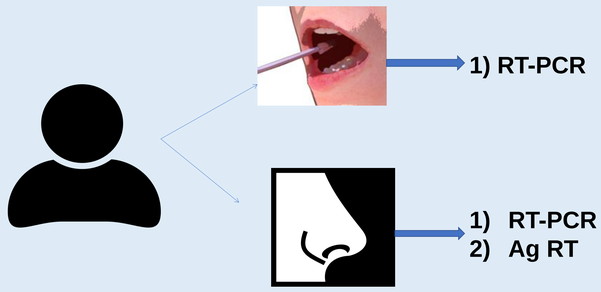
BACKGROUND

Nasopharyngeal swabs (NPS) samples are the cornerstone for the control of the COVID-19 pandemic, but this sample is **annoying and generates anxiety,** especially in children.

We **aimed** to evaluate the adequacy of oral saliva swab analysis using RT-PCR comparing to NPS by RT-PCR and Antigen Rapid Test (AgRT) in NPS in children.

METHODS

- Cross-sectional multicenter diagnostic study
- February and March 2021
- 10 hospitals in Spain
- Symptomatic children 0-18 years
- ≤5 days of duration attending at emergency departments
- Three samples



In patients with **discordant results**, new NPS was collected for viral culture and original samples were tested for viral RNA subgenomic (sgRNA) study.

Bayesian model was used to estimate the accuracy assuming that RT-PCR in NPS is not a perfect gold standard.

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RT-PCR on oral saliva swab is a friendly option for SARS-CoV-2 testing in children and it is more accurate (SSB 84.8%) than Ag Rapid test widely used (SSB 72.5%)

RESULTS

- 1174 children
- Aged 3.8 years (IQR, 1.7-9.0),
- 647/1174 (55.1%) male
- 760/1174 (64.7%) fever 1 day before emergency department admission (IQR 1.0-2.0)

73/1174 (6.2%) patients tested positive in at least one of the techniques. Accuracy is in Table 1.

Kappa index

- RT-PCR oral saliva swab vs. RT-PCR NPS was 0.80 (0.72-0.88)
- AgRT vs RT-PCR in NPS was 0.74 (0.65-0.84)

The Cts were higher in oral saliva swabs compared with NPS; being Ct (NPS) = 0.5 x (Ct saliva) + 4.5 (p=0.027).

Overall, 4 (10.8%) patients with discordant results had a positive culture. In 3 of the 4 patients, the discordance was positive on oral saliva swab and nasopharyngeal swabs RT-PCR but negative by antigen rapid diagnostic test.

Parameters	NPS RT-PCR (assumed as a perfect gold standard (%)*	Bayesian latent class model (%) **
Prevalence	5.8 (4.6 - 7.3)	5.0 (3.8 - 6.4)
RT-PCR NPS		
Sensitivity	100	99.3 (92.1 - 100)
Specificity	100	99.1 (98.3 - 99.7)
Positive Predictive Value	100	84.4 (73.3 - 94.6)
Negative Predictive Value	100	100 (99.6 - 100)
RT-PCR oral saliva swab		
Sensitivity	72.1 (59.7 - 81.0)	84.8 (71.5 - 93.6)
Specificity	99.6 (99.0 - 99.9)	99.7 (99.2 - 99.9)
Positive Predictive Value	92.5 (80.9 - 97.6)	92.6 (83.3 - 98.3)
Negative Predictive Value	98.3 (97.3 - 98.9)	99.2 (98.4 - 99.7)
Antigen Rapid Test		
Sensitivity	61.8 (49.1 - 73.0)	72.5 (58.8 - 83.6)
Specificity	99.9 (99.4 - 100)	99.9 (99.6 - 100)
Positive Predictive Value	97.7 (86.2 - 99.9)	97.6 (89.9 - 100)
Negative Predictive Value	97.7 (96.6 - 98.5)	98.6 (97.6 - 99.2)

* Gold standard model assumed that RT-PCR NPS test is perfect (100% sensitivity and 100% specificity; all patients with positive gold standard test are diseased and all patients with negative gold standard test are non-diseased). Values shown are estimated means with 95% confidence interval.

** Bayesian latent class model assumed that all tests evaluated are imperfect. Values shown are estimated median with 95% credible interval.

RT-PCR: reverse transcriptase polymerase chain reaction; NPS: nasopharyngeal swab;

Table 1

CONCLUSIONS

RT-PCR on oral saliva swab is an accurate option for SARS-CoV-2 testing in children. A friendlier technique for younger patients, who must be tested very frequently, may help to increase the number of patients tested.

ADDITIONAL KEY INFORMATION

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