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LETTER TO THE EDITOR

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Evaluation of rapid antigen tests based on saliva for the detection of SARS-CoV-2

Echavarria et al.[1] presented in their paper the noninvasive saliva sampling as an alternative for nasopharyngeal (NP) swabs for RT-PCR-based detection of SARS-CoV-2 in the emergency room. The utility of saliva for the detection of SARS-CoV-2 was demonstrated in other recent studies as well.[2–4] A disadvantage is the need for the RT-PCR resulting in a long time until result which may be problematic, especially in emergency rooms. To address this problem, in this study a rapid antigen test (RAT) CE-certified for the detection of SARS-CoV-2 using saliva (COVID-19 Antigen Test Cassette [hypersensitive colloidal gold]; Xiamen Zhongsheng Langjie Biotechnology Co., Ltd.) was evaluated.

The study was approved by the local ethic committee (EK-20-356-0121) and took place from January 15 to January 17, 2021, when healthy citizens of Vienna, Austria were invited to participate in a voluntary SARS-CoV-2 mass screening, based on a SARS-CoV-2 RAT using NP swabs.

RT-PCR (SARS and Wuhan CoV E-gene) from a gargle sample (10 ml saline gargled for 30–60 s) was done to confirm positivity in all patients testing positive with the NP swab RAT, as well as in subjects who did not tolerate the NP swab sampling, or in whom NP swabbing could not be performed for medical reasons. All individuals in whom gargle fluid was tested by RT-PCR were invited to participate in the study. Participants were verbally instructed to make a "KRUUA" sound in the throat to clear saliva from the deep throat and to spit it in a tube prefilled with buffer (at least 2 ml saliva). The attending health care professional performed the saliva RAT following the manufacturer's instructions. The result was read within 15 min.

Forty subjects agreed to participate in the study (18 with positive RAT results of NP swab and 22 not undergoing NP sampling). The median age of participants was 44 years (range: 7–79 years), 50% were female. After a comprehensive interview, 27.5% of the supposedly healthy subjects reported mild symptoms including tiredness or aches; the meantime from symptom onset was 3 days.

The overall sensitivity of saliva RAT was 44.4% (8/18) compared with RT-PCR results from gargle solution as the gold standard. The five gargle-samples with CT value ≤25 yielded a sensitivity of 60%, in samples with CT value ≤30 42.8%. No significant difference in sensitivity was seen between symptomatic and asymptomatic individuals (45.5% vs. 42.8%, respectively). The specificity of saliva RAT compared to RT-PCR of gargle solution was 100%. Our data is similar to the results of Schildgen et al.[5] who showed a sensitivity of different RATs performed on gargle sample between 33.3% and 88.1%. However, the authors did not evaluate saliva.

In summary, self-testing with RAT and saliva allows cheap, simple, and fast testing for SARS-CoV-2. In several countries, for example, Austria, the evaluated saliva RAT is commercially available and licensed for self-testing at home. However, the authors postulate that RATs based on saliva for the detection of SARS-CoV-2 are not a reliable substitute for RT-PCR. Our data suggest that even individuals with high virus load may not be detected by saliva RAT. A negative saliva RAT test cannot confirm the absence of SARS-COV, a confirmation with RT-PCR is needed. A person with a false negative saliva RAT entering for example an elderly care facility as a visitor may cause serious harm to the residents in those facilities.

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