Rapid antigen detection testing for universal screening for SARS-CoV-2 in women admitted for delivery

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Title:

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The authors declare that they have no conflicts of interest.

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Objective

In the recent year, the rapidly emerging severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic has posed major challenges on public health systems [1]. Timely detection of cases is considered crucial to help forestall this unprecedented Coronavirus Disease 19 (COVID-19) pandemic. This is of utmost importance in the obstetric population, as these women have multiple interactions with the health care systems as well as with other parturients when admitted for delivery. Hence, universal screening for SARS-CoV-2 was suggested as useful means among women presenting for delivery [2]. The gold-standard recommended diagnostic method for SARS-CoV-2 is real-time reverse-transcription PCR (RT-PCR) [3]. Nevertheless, the laboratory capacities to perform RT-PCR in a timely manner in this setting are limited, calling for alternative assays. The introduction of rapid detection tests (RDTs) was suggested as a useful means for earlier detection of positive cases [4]. We aimed to evaluate the performance of an antigen-based RDT for universal screening for SARS-CoV-2 in women admitted for delivery.

Study Design

A prospective study following asymptomatic women admitted for delivery between October 21 and December 28, 2020 in a university affiliated hospital in Israel. At the time of admission, nasopharyngeal swabs from all women were collected for universal screening for SARS-CoV-2 using an antigen-based RDT (NowCheck COVID-19 Ag Test, Bionote Inc., Republic of Korea). All women were co-tested using the gold-standard RT-PCR on the NeuMoDx 288 molecular system (NeuMoDx™ Molecular, Ann Arbor, Michigan). The institutional review board approved this study.

Results

A total 1326 parturients were included and co-tested at their time of admission using both an antigen-based RDT and RT-PCR. Of them, 9 (0.7%) were positive for SARS-CoV-2 using RT-PCR. Of the latter, 5 had a positive result using the antigen-based RDT, while the other four were tested negative (i.e. false negative), resulting in a sensitivity of 55.6% (95% CI 21.2%-86.3%). Among the 9 women tested positive for SARS-CoV-2 using RT-PCR, all those who were also tested positive by the antigen-based RDT had a cycle threshold (Ct) value below 30 (16, 25, 28, 28, 29), whereas the four women with a negative antigen-based RDT result had a Ct value equal or higher than 30 (30, 31, 31, 33).

None of the women who were tested negative using the RT-PCR, had a positive antigen-based RDT result, resulting in a specificity of 100% (95% CI 99.7%-100.0%).

Conclusion

The use of point-of-care antigen-based RDT for universal SARS-CoV-2 screening among asymptomatic parturients, was shown in the current study to have moderate sensitivity and high specificity. The potential benefits of a universal testing approach using RDT among women admitted for delivery may allow timely determination of COVID-19 status which will guide the utilization of proper protection measures and inform neonatal care.

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Contribution to authorship:

AR, GZ, BR, DK, SB, YO, SP and YS reviewed the literature and wrote the paper. AR performed the statistical analyses for this study. AR and GZ designed the study and the prospective data collection All authors read and approved the final manuscript.

Details of ethical approval:

The study was approved by Hadassah Medical Center institutional review board.

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Authors may either sign the same form or submit individually

I am an author on this submission, have adhered to all editorial policies for submission as described in the Information for Authors, attest to having met all authorship criteria, and all potential conflicts of interest / financial disclosures appears on the title page of the submission.

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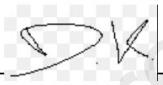
Signature: 

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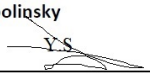
Signature: 

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