Performance of a Rapid SARS-CoV-2 Antigen Detection Assay in Symptomatic Children

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Abbott BinaxNOW (a bedside lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen) is widely available under US Food and Drug Administration emergency use authorization for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in symptomatic patients within 7 days of symptom onset. Its diagnostic performance in symptomatic children has not been evaluated.

METHODS

Cross-sectional study of symptomatic children ≤20 years presenting for care to 1 of 2 primary care practices in December 2020, during which time coronavirus disease 2019 (COVID-19) rates were particularly high (1927 cases per 100 000; 26% of all tests performed were positive).[1] The University of Pittsburgh Institutional Review Board approved the study.

Per our institution's guidelines at the time of the study, we tested consecutive children with symptoms for <7 days presenting with 1 of the following: cough, shortness of breath, difficulty breathing, loss of smell or taste, severe respiratory illness; or 2 of the following: known exposure to COVID-19, fever or chills, congestion or runny nose, body aches, fatigue, headache, sore throat, nausea, vomiting, or diarrhea. Assuming 25% of children would test positive for SARS-CoV-2 and that the sensitivity and specificity of BinaxNOW would be close to 85%, we estimated needing 196 children to produce 95% confidence intervals (CIs) no wider than +/−10% around test sensitivity.[2]

A total of 2 nasal (middle turbinate) swabs were obtained from each patient, 1 from each nostril. One was used for in-office BinaxNOW; 1 trained reader visually interpreted test cards (any visible band was considered positive). The second specimen was placed in transport media and submitted for qualitative real-time polymerase chain reaction (PCR) for SARS-CoV-2 RNA by using Roche Cobas or Hologic Panther platforms at a local Clinical Laboratory Improvement Amendments–approved laboratory.

We calculated accuracy of BinaxNOW using PCR results as the reference standard using Stata 16 (Stata Corp, College Station, TX). Because, in previous studies, researchers have suggested relatively higher viral loads in younger children,[3] we explored the effect of age on test accuracy.

RESULTS

A total of 199 children aged 2 months to 20 years were included; 39 had a positive PCR for SARS-CoV-2. The sensitivity and specificity of BinaxNOW were 0.85 (95% confidence interval: 0.70–0.94) and 0.91 (95% CI: 0.86–0.95), respectively (Table 1). The

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Dr Shaikh conceptualized the study, designed the study, analyzed the data, and drafted the initial manuscript; Drs Tate and Friedlander collected data and reviewed and revised the manuscript; Drs Wells and Chang and Ms Liu analyzed the data and reviewed and revised the manuscript; Dr Hoberman conceptualized the study, designed the study, analyzed the data, and reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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TABLE 1 Accuracy of BinaxNOW for SARS-CoV-2 Infection According to Age

	No. Children	No. With SARS-CoV-2	Sensitivity (95% CI)	Specificity (95% CI)	Positive Predictive Value (95% CI)	Negative Predictive Value (95% CI)
Children of all ages	199	39	85 (70–94)	91 (86–95)	70 (55–83)	96 (92–99)
Children <7 y of age	89	11	100 (72–100)	92 (84–97)	65 (38–86)	100 (95–100)
Children 7–20 y of age	110	28	79 (59–92)	90 (82–96)	73 (54–88)	93 (84–93)

accuracy of the test was higher (P = .008) in children aged <7 years; in this age group, the sensitivity and specificity of the test were 1.00 (95% CI: 0.72–1.00) and 0.92 (95% CI: 0.84–0.97), respectively.

DISCUSSION

We provide data on the accuracy of BinaxNOW for SARS-CoV-2 in symptomatic children. The test does not seem particularly useful in children 7 to 20 years because of its suboptimal combination of sensitivity and specificity. In children <7 years, although specificity of the test was suboptimal, its high sensitivity might be useful in ruling out COVID-19. If our findings are confirmed by others, children <7 years with a negative BinaxNOW result could be allowed to return to day care or preschool. However, positive results would need to be confirmed with a PCR test, given the test's high false-positive rate.

In 2 studies, researchers examined accuracy of BinaxNOW. The first included a convenience sample of adults, 84% of whom were asymptomatic[4]; the second enrolled a community sample (73% were asymptomatic; 6% were <18 years of age).[5] In these studies, the researchers reported sensitivities in the 89% to 96% range and specificities of >99%; no differences were apparent according to age or presence of symptoms. In contrast, in our study, we included only symptomatic children with suspected COVID-19 and found similar sensitivity (except in those <7 years of age) but substantially lower specificity. Differences between results might be due to differences in test interpretation in the previous studies (interpreted the test retrospectively by using scanned images, used 2 or more readers, disregarded partial bands). The differing spectrum of patients could also have influenced accuracy.[6]

The strengths of our study include determining the test performance in the same setting that it would be used in practice. The limitations include lack of cycle threshold data for the PCR test. In conclusion, with the use of the BinaxNOW rapid antigen test, one must consider potentially high rates of false-positives and the age of the target population before using it as a stand-alone assay.

ABBREVIATIONS

CI: confidence interval
COVID-19: coronavirus disease 2019
PCR: polymerase chain reaction
SARS-CoV-2: severe acute respiratory syndrome coronavirus 2

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