Evaluation of a rapid antigen detection test for the diagnosis of group-A beta-hemolytic *Streptococcus* in pharyngotonsillitis

Sir,

Among the beta hemolytic *Streptococci* causing pharyngitis, group-A *Streptococcus* (*Streptococcus pyogenes*) is the most common etiological agent affecting children five to fifteen years of age, accounting for 10-30% of the cases in children.\(^1\) In addition, the various infections caused by group-A *Streptococcus*, post streptococcal non-suppurative sequelae, such as, acute rheumatic fever and glomerulonephritis, are of major concern.\(^2\) In this context, whether or not to treat a patient with suspected group-A streptococcal pharyngitis on day 1 of the outpatient visit or wait for the culture results is always a dilemma, and poses a diagnostic challenge for the treating physician.

Various studies have evaluated the sensitivity and specificity of kits such as STREP A OIA MAX, AbbottTest Pack Plus Strep A, BioStar Strep A OIA, and Strep A OIA, available in the market, to diagnose group-A streptococcal pharyngitis. One such study is a Korean study, which evaluated the SD Bioline Kit (Yongin, Korea).\(^3\) As there is insufficient information on these rapid kits from India, we carried out this study to evaluate the sensitivity and specificity of the SD Bioline rapid antigen test to detect group-A beta-hemolytic *Streptococcus* in parallel with throat cultures. This test, which is based on immunochromatography, is a qualitative test for detection of the group-A streptococcal antigen. A total of 111 throat swabs sent to the Clinical Microbiology Department for routine culture were included in the study. The test was performed according to the manufacturer's instructions. Throat swabs for culture were inoculated onto blood agar plates and incubated in a CO2 incubator at 37°C. Grouping of beta-hemolytic *Streptococci* was done using the coagglutination technique after the antigen was extracted by the micronitrous acid extraction method.

Out of the 111 samples tested, 27 grew group-A *Streptococcus* in the culture. However, only 15 (13.5%) of the 27 group-A *Streptococcus*-positive samples were positive by the SD Bioline (Yongin, Korea) rapid antigen test. Among the samples that were negative by the rapid test, seven showed a heavy growth of group-A *Streptococcus* on culture, three had moderate growth, and two had scanty growth. There were no false positives due to other groups of *Streptococci* or with other organisms. The kit showed a sensitivity of 55.5% and specificity of 100%, however, the Korean study done in 2009, showed a sensitivity of 95.9%.

With the sensitivity just over 50%, the validity of the test is questionable, as a clinical decision to treat or not treat pharyngitis becomes difficult, unless there is a culture report. Various rapid tests are available to the physician in the market, which are capable of getting results in 15 minutes. False-positive conditions, such as, *Streptococcus milleri* group strains that express a group-A carbohydrate antigen, nutritional variants of group-A *Streptococci* or non-hemolytic group-A *Streptococci* should be considered.\(^4\) False negatives due to misidentification of beta-hemolytic organisms that lack a group-A carbohydrate antigen should also be ruled out.

Studies have shown that the latent period between the onset of a preceding streptococcal sore throat and the onset of acute rheumatic fever is around 19 days.\(^5\) Therefore, in settings where no culture is available, rapid tests may be an alternative, but antibiotic treatment...
should be definitely based on a culture, which is the gold standard.

To our knowledge, this is the first Indian study done to evaluate an SD Bioline rapid antigen test to detect group-A *Streptococcus* from throat cultures in acute pharyngitis in children.

Beula Subashini, Shalini Anandan, Veeraraghavan Balaji

*Department of Clinical Microbiology, Christian Medical College and Hospital, Vellore - 632 004, Tamil Nadu, India*

**Address for correspondence:**
Dr. Shalini Anandan,
E-mail: shalinianandan@cmcvellore.ac.in

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