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## RAPID ANTIGEN TESTING FOR STREP SORE THROAT



Pediatrics		
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## **ABSTRACT**

This was a cross sectional study to estimate the prevalence of Group A Streptococcal (GAS) infection among children with acute sore throat and to compare results of Rapid antigen detection test (RADT) with throat culture. Children aged 3-15 years who presented with acute sore throat (throat pain  $\pm$  redness of pharynx, palate, tonsils), whose parents were willing to participate in the study by giving a written consent were included. Two sterile throat swabs were taken by vigorously rubbing the tonsils or posterior pharyngeal wall, one for RADT (cerTEST Strep A card test) and 2nd for bacterial culture. The samples were sent to the in-hospital NABL certified laboratory (SRL Ltd). The results of RADT were obtained within 15 minutes while the culture report was available after 72 hours. During the 7 months study period we took 90 throat samples from 86 children. Of these 26 were RADT positive and 22 were culture positive. The prevalence of GAS by RADT was 28.88% and by culture was 25.56%. The sensitivity and specificity of RADT was 95.65% and 94.02% respectively. Since the RADT had high sensitivity and specificity and the results were available within 15 minutes, the need for throat swab culture (with additional cost and delay in results) could be avoided. Appropriate antibiotic may be started on the basis of RADT. If RADT is negative culture should be sent.

## **KEYWORDS**

Group A Streptococci (GAS), Rapid Antigen Detection Test (RADT), Sore throat, Throat culture.

Acute sore throat is a common presenting symptom among children age 3-15 years presenting in the Pediatric OPD (Graham 2011). Approximately three- fourths are viral and one- fourth are bacterial in etiology (Anjos, Marcondes, Lima, Mondelli, Okoshi 2014), (Bisno, Gerber, Gwaltney, Kaplan, Schwartz 2002). Since the treatment, course and complications are different in the two groups, it is important to differentiate between the two as early as possible. Two validated clinical scoring systems which aid in the diagnosis of GAS are modified Centor (McIsaac) and Toronto scores (Choby 2009), (Graham 2011). Since the clinical scoring systems alone may not reliably differentiate between the two, the Infectious Diseases Society of America (IDSA) 2012 recommended the use of pharyngeal swab culture or RADT to guide antibiotic usage (Shulman et al., 2012).

#### Methods

After clearance from the Institutional Ethics Committee the parents of all children age 3-15 years who presented to the Pediatric OPD with acute sore throat (throat pain  $\pm$  redness of pharynx, palate, tonsils) were counseled regarding the usefulness of RADT and throat swab culture in differentiating between bacterial and viral etiology and guiding the treating doctor whether an antibiotic for 10 days is necessary or not. Exclusion criteria included consent not given or alternative diagnosis made. Between December 2014 and June 2015 we were able to get 90 throat swab samples from 86 children. Two throat swab samples were collected, one sample each for RADT and bacterial culture. The sterile swabs were vigorously rubbed on the tonsils or posterior pharyngeal wall taking care to avoid contact with the teeth, gums, tongue and cheek.

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Samples were processed at the in-hospital NABL certified SRL laboratory as soon as possible. RADT is a qualitative immunochromatographic assay. It was done on CerTest Strep A card from Biotec. Once the kit was removed from its sealed bag it was allowed to reach room temperature (15-30°C). 5 drops of Reagent A (light pink) and 5 drops Reagent B were mixed in a test tube. The solution should turn light yellow. The swab was immediately put into the tube and the solution mixed by rotating and squeezing the swab forcefully against the side of the tube for at least 1 minute. The best results are obtained when the specimen is vigorously extracted into the solution. The swab was then withdrawn and discarded. Using a pipette 4 drops of the solution from the test tube were put into the circular window marked with the letter S. The result was read at 10 minutes.

Sheep Blood agar (SBA) was used for the isolation of GAS, the plates were incubated for 48 hours at 37°C under anaerobic atmosphere, containing 5-10% CO2.examined for the presence of beta-hemolysis. The organism obtained on SBA was identified by an automated Culture ID/AST system-Vitek 2 Compact (Biomereiux).

Data entry and analysis was made by using software STATA 9 (StataCorp, Texas, USA) version. All clinical variables were represented in the form of numbers and percentages. Chi square test was applied for establishing association and P value < 0.005 was considered as significant.

The cost of Throat swab culture was Rs. 1260.00 and the subsidized cost of RADT for the purpose of the study was Rs. 610.00.

#### Results

None of the children was on antibiotics prior to throat swab sampling. Mean age of the children was  $79.12\pm32.98$  months. Mean duration of illness at presentation was  $3.07\pm1.8$  days. One child had 3 episodes of RADT positive sore throat with culture positive twice and negative once. Another child had 2 episodes of RADT positive sore throat. The prevalence of GAS by RADT was 28.88% and by throat culture was 25.56%. The sensitivity and specificity of RADT was 95.65% and 94.02% respectively (Table 1). Of the 26 RADT positive throat swabs, 22 were culture positive and 4 culture negative.

#### Discussion

Clinical scoring systems such as modified Centor [McIsaac] and Toronto scores do not clearly differentiate between viral and bacterial acute sore throat. Therefore, IDSA in 2012 recommended use of throat swab RADT and bacterial culture to confirm bacterial sore throat in order to guide appropriate use of antibiotic (Shulman., et al 2012). Many studies have been done in the past on sensitivity and specificity of RADT and throat culture (Table 2). The variation in sensitivity can be explained by the method of obtaining throat swab samples, expertise in performing the test and inoculum size (more with heavy than with light inoculum). Throat culture is the gold standard for diagnosing pharyngitis caused by GAS and is reported to have a sensitivity ranging between 90% and 95% (Anjos., 2014).

Nandi S, et al (2001) in their study of the periurban population of northern India, reported sore throat and GAS in 7.05 and 0.95 episodes per child year. The incidence was higher among 11- RAPID ANTIGEN TESTING FOR STREP SORE THROAT year olds, during

the winter and rainy months (a bimodal peak), among children living in houses where there was no separate room for the kitchen, and in homes that included a tobacco smoker.

(Kumar, Vohra, Chakraborty, Sharma, Dhanda, Sagar, et al 2009) did an eight year prospective surveillance in Rupnagar district of Punjab, a registry based control project. The prevalence of GAS was 2.8% in children with sore throat and 1.3% among those not having sore

Shah R, et al (2011) suggested that throat swab culture and rapid antigen testing are useful for making a diagnosis of GAS pharyngitis but the RADT may not be available in resource poor settings.

In our study the prevalence of GAS was 28.88% and 25.56% (by RADT and culture respectively) among children presenting in the OPD with sore throat. RADT sensitivity and specificity was 95.65% and 94.02% respectively. Most RADTs that are currently available have high specificity (95% or greater). This means that false positive test results are unusual and therefore therapeutic decisions can be made on the basis of a positive test with a high degree of certainty. The sensitivity of most of the currently available RADTs is between 70 and 90%. A negative test does not exclude GAS and it is therefore recommended that a negative RADT be confirmed with a throat culture.

#### Limitations of study

- 1. Our study was performed at a private corporate hospital, hence the study population may not be representative of the general population.
- The study was done in the winter months during which streptococcal sore throats are more common, hence our study may overestimate the prevalence.
- The estimated sample size was 300, calculated by taking prevalence of streptococcal sore throat as 25% and allowable error 5% by using formula: n = 4pq/d2, but we were able to test only 90 sore throat samples in our study.

#### Conclusions of study

The sensitivity and specificity of RADT was 95.65% and 94.02% respectively and the result was available within 15 minutes. Therefore, Pediatricians in office practice may be encouraged to use RADT more often for early diagnosis of Strep sore throat to guide antibiotic usage. Rapid identification and treatment of children with GAS sore throat will reduce the risk for spread of infection, allowing them to return to school earlier, and will reduce the acute morbidity of the illness.

TABLE-1 Comparison of results of RADT and throat swab culture

RADT (n)	Throa	t culture
	Positive n (%)	Negative n (%)
Positive (26)	22 (95.6)	4 (6%)
Negative (64)	1 (4)	63 (94%)

TABLE -2 Studies showing sensitivity and specificity of RADTs compared with throat culture.

Studies	Sensitivity	Specificity
Schlager TA, Hayden GA, Woods WA et	77%	97%
al 1996. Pediatr. Adolesc. Med.[8]		
Kaltwasser GJ, Diego PL et al 1997.	80%	89%
Pediatr. Infect. Dis. J.[9]		
Pitetti RD, Drenning SD, Wald ER 1998.	79.5%	96.9%
Pediatr. Emerg. Care.[10]		
Wong MC, Chung CH 2002. Hong Kong	52.6%	98.2%
Med. J.[11]		
Uhl JR, Adamson S, Vetter EA et al 2003.	93%	98%
J. Clin. Microbiol.[12]		
Micheal A et al. 2004. Clinical	70-90%	>95%
Microbiology Reviews.[7]		
Worrall G et al. 2011. Acute sore throat.	85%	97%
Canadian family physician.[1]		
Choby BA march 2009. Diagnosis and	90-99 %	90-99%
treatment of streptococcal pharyngitis.		
American family physician.[4]		
Our study 2014-15	95.65%	94.02%

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