



Research

Evaluation of the Efficacy of the Biogold Strep A Rapid Antigen Test for the Detection of Group A Beta-Haemolytic *Streptococci* in Throat Swabs

Boğaz Sürüntü Örneklerinde A Grubu Beta-Hemolitik *Streptokokların* Tespitinde Biogold Strep A Hızlı Antijen Testinin Etkinliğinin Değerlendirilmesi

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ABSTRACT

Objective: Group A beta-haemolytic *Streptococcus* (GAS) cause 20-40% of childhood pharyngitis and 5-15% of adult pharyngitis. Without timely treatment, GAS can lead to severe complications, such as acute rheumatic fever and post-streptococcal glomerulonephritis. Early identification is crucial for preventing these outcomes. Rapid antigen tests (RAT) have opened a very useful diagnostic field in the diagnosis and treatment of acute tonsillopharyngitis. This study aimed to assess the effectiveness of the Biogold Strep A Card test compared with the gold-standard culture method.

Methods: This study included 6,188 throat swab samples submitted between January 2022 and May 2023. Samples were tested using both the Biogold Strep A Card (Bioriver, Türkiye) and culture methods.

Results: Among 6,188 patients, 2,717 (43.9%) were female and 3,471 (56.1%) male, with a mean age of 11.8±9.6 years. Among the patients examined, 17.2% (1,062) had positive cultures, while 18.7% (1,155) tested positive by the Biogold Strep A RAT. The Biogold Strep A Card test showed a sensitivity of 75.6%, specificity of 93.1%, positive predictive value of 69.4%, negative predictive value of 94.8%, and overall accuracy of 90.1%.

Conclusion: Initiating antibiotic therapy in patients with positive RAT results may reduce the risk of complications, particularly in children aged 5-15 years. For patients with negative RAT results, avoiding unnecessary antibiotics helps prevent resistance. Culturing RAT-negative cases further minimizes misdiagnosis and incomplete treatment.

Keywords: GAS, *Streptococcus pyogenes*, throat culture, rapid antigen test

ÖZ

Amaç: A grubu beta-hemolitik *Streptokoklar* (GAS) çocukluk çağı farenjitlerinin %20-40'ına ve yetişkin farenjitlerinin %5-15'ine neden olmaktadır. Zamanında tedavi edilmeyen GAS, akut romatizmal ateş ve post-streptokokal glomerülonefrit gibi ciddi komplikasyonlara yol açabilir. Bu sonuçların önlenmesi için erken teşhis çok önemlidir. Hızlı antijen testleri (RAT), akut tonsillofarenjitin tanı ve tedavisinde çok yararlı bir tanı alanı açmıştır. Bu çalışmada Biogold Strep A Card testinin altın standart olan kültür yöntemine kıyasla etkinliğinin değerlendirilmesi amaçlanmıştır.

Gereç ve Yöntem: Bu çalışmaya Ocak 2022 ve Mayıs 2023 tarihleri arasında gönderilen 6.188 boğaz sürüntü örneği dahil edilmiştir. Örnekler hem Biogold Strep A Card (Bioriver, Türkiye) hem de kültür yöntemleri kullanılarak test edilmiştir.

Bulgular: Toplam 6188 hastanın 2.717'si (%43,9) kadın ve 3.471'i (%56,1) erkek olup yaş ortalaması 11,8±9,6'dır. İncelenen toplam hasta sayısının %17,2'sinde (1.062) kültür testi pozitif çıkarken, %18,7'sinde (1.155) Biogold Strep A RAT testi pozitif çıkmıştır. Biogold Strep A Card testi %75,6 duyarlılık, %93,1 özgüllük, %69,4 pozitif öngörü değeri, %94,8 negatif öngörü değeri ve %90,1 genel doğruluk göstermiştir.

Sonuç: RAT sonuçları pozitif olan hastalarda antibiyotik tedavisinin başlatılması, özellikle 5-15 yaş grubunda komplikasyon riskini azaltabilir. RAT sonucu negatif olan hastalarda gereksiz antibiyotik kullanımından kaçınmak direnci önlemeye yardımcı olur. RAT-negatif olguların kültüre edilmesi yanlış tanı ve eksik tedaviyi en aza indirir.

Anahtar Kelimeler: GAS, *Streptococcus pyogenes*, boğaz kültürü, hızlı antijen testi

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INTRODUCTION

Approximately 16% of adults and 41% of children are diagnosed with pharyngitis annually (1). Group A beta-haemolytic *Streptococcus* (GAS) [*Streptococcus pyogenes* (*S. pyogenes*)] is the most prevalent bacterial cause of infectious pharyngitis. It is estimated that GAS is responsible for 20 to 40% of cases of pharyngitis in children and 5 to 15% in adults (2,3). The most common symptoms of the disease are sore throat, fever, tonsillar exudates, and swollen cervical lymph nodes. As the symptoms of bacterial pharyngitis are similar to those of viral pharyngitis, diagnosis based on clinical features alone (4). Although scores such as Centor and Mclsaac have been developed to facilitate clinical decision-making in the diagnosis of GAS pharyngitis, the use of culture and rapid antigen tests (RAT) is necessary to obtain evidence-based results (1,5).

If GAS pharyngitis is not treated in a timely manner, it may result in an increase in the prevalence of suppurative and non-suppurative complications, including acute rheumatic fever (ARF), rheumatic heart disease, post-streptococcal glomerulonephritis, bacteremia, peritonsillar abscess, and retropharyngeal abscess, as well as increased mortality rates (6). It is therefore of utmost importance to rapidly detect the presence of GAS in order to prevent the adverse complications that may result (3).

The most reliable method for diagnosing GAS is the culture of a throat swab. However, the lengthy diagnostic period, which can take 24-48 hours, significantly limits the effective utilisation of the throat culture method (6,7). This presents a considerable challenge in low-income countries, where patients are less likely to return to the clinic for follow-up and treatment (8). RATs have been developed for this purpose, providing results within a short timeframe, thereby facilitating prompt administration of targeted treatment. The administration of targeted therapy is also advantageous in preventing the emergence of antibiotic resistance.

Currently, numerous RATs are available, each employing a distinct methodology to detect GAS antigens (7). The most commonly employed RATs in clinical practice are enzyme-based and use immunochromatographic (lateral flow) methodology. The tests are based on the detection of Lancefield group A carbohydrates, which are GAS-specific cell wall antigens (3,4). The diagnostic sensitivity of these tests ranges from 59% to 100%, while their specificity ranges from 54% to 100% (4). A negative test result does not definitively rule out the diagnosis of GAS and necessitates performing an additional throat culture (9).

The objective of this study was to assess the diagnostic accuracy of the Biogold Strep A Card test (Bioriver, Türkiye), a rapid assay to detect GAS in throat swab samples, compared with GAS culture results in patients with a preliminary diagnosis of acute tonsillopharyngitis.

METHODS

The present study encompasses 6,188 throat swab samples obtained from patients with a preliminary diagnosis of pharyngitis and sent to our laboratory between January 2022 and May 2023. As previously stated, the samples were cultured simultaneously with RAT. Sampling was conducted with two swabs (Microcult, Türkiye) to sample both tonsils and the posterior pharyngeal wall. One was used culture, and the other for RAT detection. The Biogold Strep A Card test (Bioriver, Türkiye), which is based on a lateral-flow immunoassay, was employed to detect the GAS antigen in throat swabs. The samples were inoculated on 5% sheep blood agar and incubated at 37 °C in a 5-10% CO₂ incubator for up to 48 hours. Identification was achieved by bacitracin sensitivity testing, latex agglutination, PYR testing, and matrix-assisted laser desorption/ionisation time-of-flight mass spectrometry. A clinical isolate of *S. pyogenes*, previously identified by molecular methods, was employed for quality control purposes.

Ethics Approval

This study was approved University of Health Sciences Türkiye, Şişli Hamidiye Etfal Training and Research Hospital Clinical Research Ethics Committee (approval no: 4503, date: 20.08.2024).

Statistical Analysis

Statistical calculations and data processing were performed in Python using the NumPy and Pandas libraries. Qualitative data were compared using the chi-square test and McNemar's test.

RESULTS

The study included 6,188 patients, of whom 2,717 (43.9%) were female and 3,471 (56.1%) were male. The age range of the patients was 1-87 years, with a mean age of 11.8±9.6 years. A total of 5,418 samples (87.6%) were derived from paediatric clinics, of which 4,177 were derived from paediatric emergency departments, and 770 samples (12.4%) were derived from adult clinics. A total of 6,188 patients with a preliminary diagnosis of pharyngitis underwent throat culture and RAT in our laboratory. Of the total number of patients examined, 17.2% (1,062) tested positive for culture, while 18.7% (1,155) tested positive for Biogold Strep A RAT. Table 1

presents a comparative analysis of the results obtained from culture and RAT testing across all age groups. The distribution of patients with positive culture results by age group is as follows: 29 patients were under 5 years of age, 998 patients were between 5 and 15 years of age, and 35 patients were over 15 years of age. Table 2 presents a comparative analysis of culture and RAT test results in the 5-15-year age group. By gender, the culture positivity rate was 16.8% among females and 17.3% among males. No significant difference was observed in the distribution of positive results ($p>0.05$). The statistical results of the Biogold Strep A Card test compared with culture are as follows: sensitivity, 75.6% and 76.0%; specificity, 93.1% and 92.0%; positive predictive value, 69.4% and 73.1%; negative predictive value, 94.8% and 93.4%; and test accuracy, 90.1% and 88.9% in the general population and in patients aged 5-15 years, respectively.

DISCUSSION

The Biogold test was found to be a valuable tool for patient treatment planning, with a sensitivity of 75.6% and a specificity of 93.1% when compared with culture, which is considered the gold standard.

Acute pharyngitis is frequently caused by viral infections. As the clinical manifestations of viral pharyngitis and GAS pharyngitis are similar, a decision based on clinical features alone is not always accurate (6). Given the absence of a vaccine against GAS, the disease can only be prevented and treated with antibiotics (10).

The prescription of antibiotics based solely on clinical findings, in the absence of appropriate diagnostic tests, results in avoidable medical costs and an increase in antibiotic resistance. While the average prevalence of GAS in patients with pharyngitis in developed countries is approximately 25%, reported antibiotic prescription

rates are two to three times higher (6,11,12). Furthermore, the emergence of specific mutations in GAS has been demonstrated to reduce penicillin susceptibility (13-15). Therefore, employing sensitive, specific, and rapid microbiological diagnostic tests that provide reliable evidence to prevent the emergence of antibiotic resistance.

The majority of patients included in this study were children. GAS pharyngitis is a self-limiting infectious disease. Nevertheless, the primary objective of therapy is to prevent the development of suppurative and non-suppurative complications in paediatric patients. The administration of antibiotics is essential for reducing the duration and severity of symptoms, limiting the spread of the disease, and, most crucially, preventing non-suppurative complications such as ARF (16).

RAT was developed as an alternative to culture, which is currently regarded as the gold standard method for diagnosing the disease. It is a lateral-flow immunoassay that detects GAS antigen directly from throat swab samples within five minutes (4). RATs offer several advantages, including speed, ease of use, reduced risk of complications through earlier treatment initiation, and prevention of unnecessary antibiotic use (17).

In the meta-analysis conducted by Cohen et al. (3), 116 different RATs were analyzed across 98 publications. All participants underwent both a RAT and a throat culture, and the mean sensitivity and specificity of RATs were reported as 86% and 95%, respectively (3). In the study by Sølvik et al. (4), two distinct RATs were compared. A comparative methodology, utilising the culture of *S. pyogenes* as the reference standard, was employed. The diagnostic sensitivities of the QuickVue® Dipstick Strep A test and the DIAQUICK Strep A Blue Dipstick were 92% and 72%, respectively; the diagnostic specificities were 86% and 98%,

Table 1. Comparison of culture and rapid antigen test for all age groups

		Culture		
		Positive	Negative	Total
Rapid antigen test	Positive	802	353	1155
	Negative	260	4773	5033
	Total	1062	5126	6188

Table 2. Comparison of culture-rapid antigen test in 5-15 age group

		Culture		
		Positive	Negative	Total
Rapid antigen test	Positive	758	279	1037
	Negative	240	3396	3636
	Total	998	3675	4673

respectively. The findings indicated that both RATs exhibited satisfactory performance in this study (4).

In a further study published in 2019, the diagnostic accuracy of the QuickVue® Dipstick Strep A test was evaluated in children with acute tonsillopharyngitis. Two throat swabs were obtained RAT and culture. The culture method demonstrated that the sensitivity and specificity of the QuickVue® Dipstick Strep A test were 100% and 98%, respectively (18).

The sensitivity and specificity of the RAT included in the study were found to be 75.6% and 93.1%, respectively. Upon evaluation of the results, it was determined that the performance of the RAT test was adequate for the intended purpose. In the 5-15-year age group, the sensitivity and specificity of the RAT were 76.0% and 92.0%, respectively. These findings demonstrate that the selected RAT exhibits consistent performance in accurately detecting patients with a positive GAS result across all age groups.

A study revealed that 28% of antibiotic prescriptions for paediatric patients evaluated for pharyngitis were not in accordance with the guidelines, predominantly because antibiotics were prescribed despite negative GAS test results (19). In accordance with international recommendations, a positive RAT result can be considered a true positive, given the high specificity of the test. Conversely, in the event of a negative RAT result, it is recommended that a throat culture be conducted for confirmation, given that the sensitivity of certain RATs has been observed to decline by up to 70% (7,17,20,21).

In the present study, the specificity was 93.1% in the general population and 92.0% in the 5-15-year age group. This suggests that the test has a low probability of incorrectly classifying healthy individuals as positive (false positives). A false-positive RAT result may result from streptococcal species in the pharynx, including commensal *Streptococcus milleri* and *Streptococcus intermedius*—which express a carbohydrate antigen in common with group A streptococci—or from nutritional variants of group A streptococci or non-haemolytic group A streptococci, which are challenging to identify by culture on standard blood agar plates (17). Furthermore, research has demonstrated that the inhibition of *Staphylococcus aureus* using molecular techniques can prevent the proliferation of GAS on culture plates (22).

Although some parameters differed between the 5-15 age group and the general population when evaluated by age range, the overall performance of the test was satisfactory for both groups. The identification of streptococci has historically been regarded as the gold standard for the

diagnosis of streptococcal infections. However, there is a risk of contamination with the natural flora of the upper respiratory tract when throat swab samples are collected for culture. Furthermore, optimal sampling of both the tonsils and the posterior pharyngeal wall can be challenging in young children, with culture sensitivity potentially reduced by up to 20% when sampling is suboptimal (23,24). This consequently results in false-negative culture results. Culture performance is influenced by the conditions used for cultivation and incubation (24). Moreover, culture results cannot distinguish active infection from the GAS carrier state (17). In the present study, serological confirmation was not employed to differentiate between active infection and carrier state. The present study was designed on the assumption that all patients with positive culture results were truly infected and that no false-positive results were obtained.

Study Limitations

A potential limitation of this study is the lack of clinical data on patients, including information on antibiotic use. The lack of documentation for patients from whom only a single swab was collected constitutes a limitation for the analysis of test results. In the study, true false-positive results could not be confirmed because a second confirmation test [polymerase chain reaction (PCR) or a different RAT] was not performed on samples that were RAT-positive but culture-negative. Additionally, since no second verification test (PCR or a different RAT) was applied to samples that were RAT-positive but culture-negative, true false-positive results could not be identified. The principal strength of this study is that it examines the relationship between culture and RAT using a large number of patient samples (n=6,188).

CONCLUSION

The data presented here support the conclusion that the risk of complications can be reduced by initiating antibiotic treatment early in patients with positive RAT results in clinical settings. In patients with negative results, unnecessary antibiotic use will be avoided, reducing the development of antibiotic resistance. Furthermore, given that a fully optimised RAT has yet to be developed, implementing a culture-based approach when RAT results are negative will help avoid misdiagnosis and incomplete treatment.

GAS infection can lead to numerous complications. The full extent of the healthcare burden and its effects on the global economy remain to be elucidated. Given the aforementioned considerations, further studies are necessary to elucidate the global impact and disease burden associated with GAS.

ETHICS

Ethics Committee Approval: This study was approved University of Health Sciences Türkiye, Şişli Hamidiye Etfal Training and Research Hospital Clinical Research Ethics Committee (approval no: 4503, date: 20.08.2024).

Informed Consent: Retrospective study.

FOOTNOTES

Authorship Contributions

Concept: M.E.B., U.T., H.T., E.A., Design: M.E.B., H.T., S.P., E.A., Data Collection or Processing: M.E.B., U.T., S.R.Ş., H.T., S.P., E.A., Analysis or Interpretation: M.E.B., U.T., S.R.Ş., H.T., S.P., E.A., Literature Search: M.E.B., U.T., S.R.Ş., H.T., E.A., Writing: M.E.B., U.T., S.R.Ş., H.T., S.P., E.A.

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