Negative RADT and Bacterial Growth on Throat Culture

Urgent message: "Sore throat" is among the most common presenting complaints in urgent care. Accurate diagnosis featuring proper use of diagnostic tools is essential to ensure timely, appropriate treatment, including appropriate utilization of antibiotic agents to minimize risk for antibiotic resistance.

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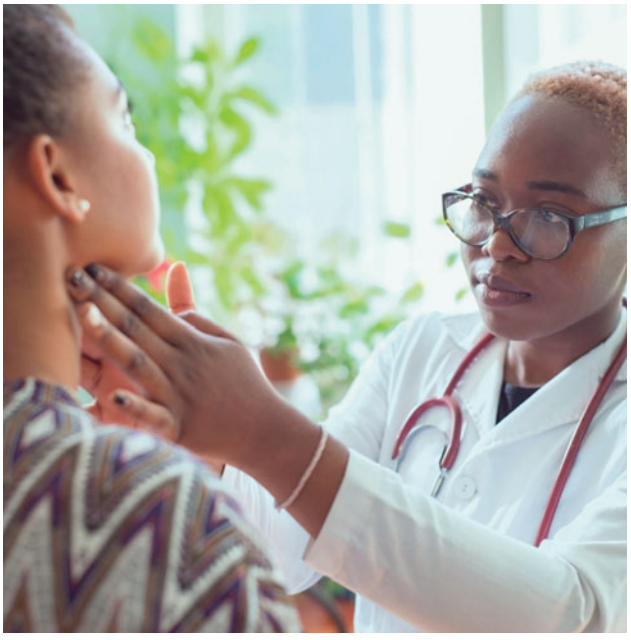
Abstract

The primary purpose of this study was to evaluate the prevalence of bacterial growth on throat culture despite a negative rapid antigen detection test. The secondary aim was to determine how often throat cultures were performed, the percentage of positive RADT, the prevalence of GAS by season and gender, whether GAS or other bacteria grew after a negative RADT and the associated prevalence, and the types of bacteria other than GAS that grew in culture.

Introduction

Acute pharyngitis is one of the most common complaints that physicians encounter in the emergency department (ED). In 2010, approximately 1.8 million ED visits involved acute pharyngitis. Among patients 15 years old or younger, it accounted for about 2.8% of all ED visits. That is roughly 700,000 cases out of the 1.8 million visits.[1]

Although most cases of acute pharyngitis are viral, bacteria still account for a proportion of cases that require antibiotic treatment. The symptoms of bacterial and viral pharyngitis tend to overlap.



Factors associated with a bacterial infection include sudden-onset sore throat, fever, tonsillopharyngeal or uvular edema, patchy tonsillar exudates, cervical lymphadenitis, exposure to Group A *beta hemolytic streptococcus* (GAS), or scarlatiniform skin rash and/or strawberry tongue, in the absence of viral symptoms.[2]

The viral symptoms of pharyngitis can include coryza, conjunctivitis, cough, hoarseness, anterior stoma-

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Table 1. Frequency of RADT Tests Performed by Season

Season	Frequency	Percentage
Fall	1,091	28.4
Winter	1,578	41.1
Spring	757	19.7
Summer	410	10.7
Total	3,836	100

titis, discrete ulcerative lesions or vesicles, and diarrhea.[3] GAS is the most common cause of bacterial pharyngitis, representing about 20%-30% of cases in pediatrics and 5%-15% in adults.[4] Although bacterial pharyngitis is mostly a benign illness, it can lead to complications that affect long-term health, such as acute rheumatic fever, rheumatic heart disease, and post-streptococcal glomerulonephritis.[2] Hence, treatment of GAS is imperative to prevent these potential complications.

Infection with GAS can result in an autoimmune condition called acute rheumatic fever. This can further affect heart valves, leading to rheumatic heart disease.[5]

The treatment of GAS may not always prevent rheumatic fever, but there is a much higher occurrence of it when the bacterium is not completely eradicated. This commonly occurs in low-income countries where aggressive treatment with appropriate antibiotics is not available.[4] In such countries, rheumatic heart disease remains the most common acquired heart disease in children, adolescents, and young adults; it accounts for roughly 233,000 deaths per year worldwide.[5] In higher-income countries, acute rheumatic fever and heart disease are rare, with less than 10 cases per year per 100,000 children. The difference is largely due to differences in living conditions, hygiene, increased antibiotic usage, increased access to primary care providers and changes in GAS epidemiology.[5]

The Infectious Diseases Society of America and the American Heart Association recommend using clinical judgment to determine who should be tested for GAS. If the need for GAS testing is unclear, the Centor criteria can be applied. Centor criteria includes age, presence of exudate or tonsillar edema, tender or swollen anterior cervical lymph nodes, presence of temperature >100.4°F and whether a cough is present. It is generally recommended to perform a rapid antigen detection test (RADT) if the modified Centor score is ≥2. The criteria should be used as a clinical tool to guide whether patients would benefit from an RADT.[2]

In order to perform an RADT, specific test swabs are used to collect a sample from the tonsillar and posterior pharyngeal mucosal surfaces. The GAS cell wall antigens are then extracted and detected using immunoassay, with results typically available within 10 to 60 minutes.[6] It is generally recommended to treat symptomatic patients with antibiotics if RADT is positive. The specificity of most available RADT is high (88% to 99%), and false positive tests are uncommon. In adults with suspected GAS pharyngitis, an RADT is usually sufficient to make the diagnosis, and additional testing such as throat cultures are not needed.[5]

Table 2. Frequency of Positive and Negative RADT

RADT	Frequency	Percentage
Positive	662	17.3
Negative	3,173	82.7
Missing	1	0
Total	3,836	100

The sensitivity of RADT in adults is moderate (77% to 92%), varying with the specific assay that is used. Because of this, the diagnosis of GAS pharyngitis could be missed if follow-up throat culture is not performed.

Overall, GAS accounts for 15% to 30% of pharyngitis in children between 5 and 15 years of age. During winter and early spring, GAS accounts for up to 35% to 40% of cases in children and adolescents. In pediatric patients, the diagnosis of GAS pharyngitis is made by a positive RADT, throat culture, or molecular assay. If initial RADT is negative a follow-up throat culture is recommended, since RADT may be falsely negative in up to 30% of cases.[3]

If initial testing with molecular assay is negative, it is not necessary to perform a throat culture, since molecular assays have a high sensitivity.

Timely treatment of GAS pharyngitis in the pediatric population is necessary to prevent suppurative complications and acute rhematic fever, prevent disease transmission, and reduce duration and severity of symptoms. It is vital to confirm the diagnosis of GAS pharyngitis prior to the initiation of antibiotics in order to prevent unnecessary antibiotic treatment in patients with viral pharyngitis.[3]

The confirmatory throat culture takes roughly 24 to 48 hours to result. The sensitivity of throat culture is between 90% and 95%, and the specificity ranges from 95% to 99%.[2] It is generally recommended to not empirically treat with antibiotics while awaiting throat culture results. The short delay in treatment does not appear to correlate with an increased risk of acute rheumatic fever in adults. However, it is unknown whether this short delay is asso-

Table 3. Frequency of Throat cultures Performed

Throat culture performed	Frequency	Percentage
Yes	3,168	82.6
No	666	17.4
Total	3,834	99.9
Missing	2	0.1
Overall Total	3,836	100

Table 4. Throat Culture Results After Negative RADT

Throat culture result after negative RADT	Frequency	Percentage
GAS +	10	0.3
GAS -	3,158	82.3
Total	3,168	82.6
Missing (+ RADT)	668	17.4
Overall Total	3,836	100

ciated with increased risk of other complications, such as the development of a peritonsillar abscess.

If the clinical suspicion of GAS pharyngitis is high and the testing results are not readily available, it is reasonable to initiate treatment with antibiotics until results return. If the diagnosis of GAS pharyngitis is not confirmed, it is recommended to discontinue antibiotics. PCR-based assays have a higher sensitivity than RADT or culture, but are not routinely available in the ED.[2]

The question of whether to treat all patients with sore throat with antibiotics is controversial. GAS has an asymptomatic carrier rate of up to 20%. Due to increasing rates of antibiotic resistance and potential for side effects and allergic reactions to antibiotics, it is recommended to avoid prescribing them for mild viral self-limiting illnesses.[4] Antibiotic treatment is not recommended for chronic asymptomatic GAS carriers or GAS carriers with superimposed viral infections.[7] Ultimately, the decision to treat patients with antibiotics is made clinically by the provider, with the above factors taken into consideration.

The primary purpose of this study was to evaluate the prevalence of bacterial growth on throat culture despite a negative RADT. The secondary aim was to determine how often throat cultures were performed, the percentage of positive RADT, the prevalence of GAS by season and gender, whether GAS or other bacteria grew after a negative RADT and the associated prevalence, and the types of bacteria other than GAS that grew in culture. This information is critical to help guide clinicians regarding when to prescribe antibiotics to prevent their overuse and to reduce antibiotic resistance.

Materials And Methods

Study Design, Setting, and Selection of Participants

This was a retrospective cross-sectional study conducted at a rural community hospital ED in Lumberton, NC. This facility has a volume of roughly 61,000 patients annually. The study setting was UNC Health Southeastern ED, involving review of medical records from November 5, 2017 to October 31, 2018. The medical chart review spanned 12 months in order to incorporate all four seasons of the year. Eligibility was based on whether the patient had received a rapid antigen detection test, also known as rapid strep test, for suspected pharyngitis. Due to the large number of patient records meeting the inclusion criteria, those who were less than 10-months-old were excluded. Moreover, a randomization was performed to select a representative study.

Study Variables

The primary outcome of this study was the prevalence of bacterial growth on throat culture in the presence of a negative RADT. In addition, we assessed for the percentage of throat cultures performed, percentage of positive RADT, and prevalence of GAS by season and gender, whether GAS or other bacteria grew after a negative RADT and the associated prevalence, and the types of bacteria other than GAS that grew in the culture.

Data Analysis

For ease of analysis, a randomization generator was applied to select a representative sample size from the high volume of medical records that met the inclusion criterion. Descriptive statistical analyses involving frequencies/percentages and a Chi-squared test for difference in proportions were performed. Data was analyzed using SPSS (IBM, Chicago, version 26).

Results

Demographics

A total of 3,836 medical records of unique patients were included in the study. The mean age was 26.4 years old with a standard deviation of 21.1 years. Out of the total, 1,577 (41.1%) patients were male. Since the study was designed over a 12-month time course, the frequency of testing in each season was performed. The majority of rapid strep testing occurred in the winter, followed by fall, then spring, and lastly summer. **Table 1** demon-

Table 5. Throat Culture That Grew Bacteria Other Than GAS

Throat culture growing bacteria other than GAS	Frequency	Percentage
Yes	29	0.8
No	3,136	81.8
Total	3,168	82.6
"Missing"/ Positive RADT	668	17.4
Overall Total	3,836	100

strates the frequency and percentage of overall testing performed by season.

Of the total 3,836 RADT performed between November 5, 2017 and October 31, 2018, 662 returned positive and 3,173 returned negative, with one missing data point (**Table 2**). Throat cultures were performed on 3,168 (82.6%) samples out of 3,834 RADT. No throat cultures were performed on 666 (17.4%) of the RADT because 662 of them resulted positive (**Table 3**). There was a total of 3,168 throat cultures performed. Of those negative RADT with a throat culture result, 10 (0.3%) were found to grow GAS and 3,158 (82.3%) did not (**Table 4**).

Twenty-nine of the 3,168 throat cultures grew bacteria "other than GAS," accounting for 0.8% of overall throat cultures. The most common bacterium that grew out "other than GAS" was Group A *beta hemolytic streptococcus*, also known as *Streptococcus pyogenes*. In fact, GAS grew out in 27 of the 29 throat cultures (93.1%) considered not to be bacterium other than GAS, representing 0.85% of overall throat cultures performed (**Table 5**). The other two growths were the bacterium *E coli* and normal respiratory flora.

Combined with the 0.3% of positive GAS on throat cultures discussed above, the overall rate of GAS growth on throat culture despite a negative RADT was 1.15%. A statistically significant difference in proportions of throat cultures positive for bacteria despite a negative RADT, with GAS, was observed, with winter season representing the most and summer the least ($p < 0.001$).

The majority of the positive throat cultures for bacteria was done in the winter, (62.1%), followed by fall (17.2%), spring (13.8%), and summer (6.9%). A Chi-squared test of goodness-of-fit for proportions demonstrated a statistically significant difference in proportions of throat cultures performed, with winter season representing the most and summer the least ($p < 0.0001$).

Regarding RADT, out of the 662 patients that tested positive, 287 (43.4%) were males and 375 (56.6%) were females. This difference in the proportion of females that tested positive for GAS on RADT compared to males was statistically significant ($p = 0.001$).

By season, it was observed that the majority of positive RADT in patients occurred in the winter, with 300 (45.3%), followed by spring with 158 (23.9%), then fall with 132 (19.9%), and lastly summer with 72 (10.9%). Furthermore, for patients who tested positive for GAS on RADT, there was a statistically significant difference in their proportion by season, with winter being the most frequent and summer being the least ($p < 0.001$).

Discussion

The primary purpose of this study was to determine the prevalence of bacterial growth on throat culture despite a negative RADT. A total prevalence rate of 1.15% was obtained for the growth of GAS on throat culture despite a negative RADT. This comprised a 0.3% incidence of GAS growth on throat culture and a 0.85% incidence for other bacterial growth. Out of the 29 throat cultures that were positive for bacteria after a negative RADT, 93% grew GAS. Other bacteria that grew on throat culture included *E coli* and normal respiratory flora.

An observational study[8] discussed controversy regarding whether there is need for routine backup testing after a negative RADT.

Out of the 15,555 adult patients who had a negative RADT and follow-up DNA probe test, 6% (933) had a positive DNA probe. From the 933 patients who had a positive DNA probe after negative RADT, 48% (448) had received an antibiotic at the time of the visit and 52% (485) received an antibiotic prescription within an average of 2.3 days of the visit.

One reported complication, for a patient with a negative RADT who did not receive the DNA probe and developed a peritonsillar abscess, was observed. Overall, management was only altered in 3% of patients who had to return for antibiotic treatment. A high rate of inappropriate antibiotic prescriptions was demonstrated, with 56% of patients receiving an antibiotic, while only 19.5% had confirmed strep throat.

The false negative rate of RADT for the diagnosis of GAS was found to be 6%. The benefit of backup testing in adults is questionable due to the high cost, antibiotic delay, and low rate of suppurative complications.[8]

For a pediatric population, a study investigated the impact of RADT, throat culture, and point-of-care (POC) polymerase chain reaction (PCR) on the decision to

treat children with antibiotics for pharyngitis at a large pediatric clinic.

This chart review conducted at a single site during the fall and winter of 2016 to 2017 consisted of a total of 110 of 255 samples (43.1%) that were GAS positive. It involved tests from patients of 3 to 18 years of age. It was shown that RADT results were less specific and throat culture results were less sensitive than reported in established literature. This has led to increased rates of inappropriate antibiotic prescription habits and use. POC PCR had high sensitivity and specificity and rapid turnaround times, which led to more appropriate antibiotic use.[9]

It is generally recommended to obtain throat cultures despite a negative RADT in the pediatric population. In a 2012 IDSA guideline, a backup throat culture in children with a negative RADT is recommended to prevent complications such as peritonsillar abscess, rheumatic fever, and poststreptococcal glomerulonephritis.[10] Although these complications are rare in the U.S., they can be prevented if antibiotics are started within the first 9 days of infection.[11]

It is valuable to know which specific test is being performed because each test has a different sensitivity. Backup cultures are recommended when lateral-flow RADT is used because it has a wide variety of sensitivity.[10,11] Optical immunoassays or molecular tests have a much higher sensitivity and lower rate of false negative tests; therefore, these do not require a backup culture to be performed in pediatric patients. In general, if a backup culture is not performed, patients should be advised to return for a throat culture and further testing if symptoms persist for more than 5 days.[10,11]

The RADT and confirmatory throat culture are not as specific or sensitive compared with other testing options. The POC PCR test would be a more optimal test; however, it is not currently available for use in the emergency department due to its high cost. Hence, the RADT and throat culture are still the most widely used methods of testing for GAS in the ED.

It is imperative that clinicians follow the guidelines for treatment of GAS pharyngitis. A study concluded that antibiotic use for sore throat remains common, and many clinicians do not follow current guidelines for diagnosis of GAS pharyngitis. Antibiotic use overall was frequent (49.3%), but less so in combination with RADT plus throat culture (31.2%) or nucleic acid amplification test (NAAT) alone (34.5%). Antibiotic use was significantly higher with RADT alone (53.4%) or no test (57.1%). Furthermore, it was found that the diagnosis of GAS pharyngitis using RADT plus culture or NAAT alone was associated with lower use of antibiotics.[12]

In clinical application, all patients who test positive for GAS, either on RADT or confirmatory throat culture, should receive antibiotic treatment to eradicate the bacterium in order to prevent long-term complications.

According to the recommendations by American College of Physicians, it is recommended to treat empirically with antibiotics if the patient has a Centor score of 4 or higher, despite the RADT or throat culture results.[13] Clinicians should avoid prescribing antibiotics for patients with viral pharyngitis in order to help prevent further antibiotic resistance. It is necessary that clinicians follow through with positive throat cultures and treat patients with appropriate antibiotics. Patient follow-up to return for treatment is crucial; patients lost to follow-up may not receive the treatment they need if results return after they are already discharged.

Whenever bacteria other than GAS grow on throat culture, it is important that patients be treated with an antibiotic that targets each specific bacterium. If patients are treated empirically up front with antibiotic coverage for GAS prior to results of culture, the antibiotic prescribed may not eradicate the bacteria if it is a different type other than GAS.

Regarding the seasons, winter had the highest proportion of GAS and other bacterial pharyngitis, and summer had the lowest. As demonstrated in literature, GAS pharyngitis is more common in late winter and early spring.[14,15]

Females, more than males, proportionally, tested positive for GAS on RADT. The mean age for this study was 26.4 years. The most frequent age that grew out bacteria on throat culture despite a negative RADT was 27 years old, and all patients were below the age of 53 years. This is consistent with literature showing that most cases of GAS in adults occur by the age of 40 years and decline afterwards.[7] Group A *beta hemolytic streptococcus* accounts for about 5% to 15% of adult cases and 20% to 30% of cases in pediatric patients.[4] A 2010 meta-analysis found that symptomatic children 5 to 15 years of age are more likely to have throat cultures positive for GAS infection compared with younger children (37% vs 24%).[16] Additionally, the 2012 IDSA guideline stated that GAS infection is uncommon in children younger than 3 years.[10]

Limitations

There are multiple limitations in this study. One is the specificity and sensitivity of the RADT test itself. Although the RADT test is highly specific (95%), the sensitivity can vary from 70% to 90%. This is dependent on the RADT sample collection technique, sample site,

and antigen load.

Throat culture of the posterior pharynx using sheep blood agar is the gold standard for diagnosis. The throat culture sensitivity depends on the culture atmosphere and media additives, which are not standardized.

As this was a retrospective study, the RADT were obtained by multiple nurses with different levels of training, at least some of whom might have been unaware of the recommended site for testing. Therefore, the sample could have been collected from the incorrect location, thereby affecting the results of the test, and potentially yielding inaccurate results.

Throat cultures were obtained on every patient who received an RADT. For every RADT performed, a throat culture was automatically reflexed to be obtained. According to the literature, it is recommended that a second swab be obtained for throat culture analysis and that the RADT swab should not be used for culture.[2,] However, at this rural ED, the same swab is used for both the RADT and the throat culture.

Another limiting factor is that the amount of growth on the culture is unable to distinguish colonization from active infection.[17]

Another limitation could be the difficulty in ensuring adequate patient follow-up when results are pending at time of discharge in rural populations. For example, those with a negative RADT and pending throat culture at time of discharge may have difficulty returning for treatment for positive throat culture. A high proportion of the population in the location of the rural ED studied face challenges with transportation and finances, which make follow-up visits less likely to occur.

In areas where patients face these challenges, each provider may approach treatment differently. If it is thought that the patient will not be able to return for treatment if throat culture returns positive after a negative RADT, some providers may treat the patient upfront with antibiotics, while still awaiting the results. Other providers may be willing to wait for the results to return before prescribing the patient antibiotics, and verify that the patient is able to return for treatment. Since the course of treatment is determined by the clinician, patients will not all be treated with the same method.

Conclusion

The overall rate of bacterial growth on throat culture despite a negative RADT was small. Hence, the likelihood that bacteria would grow on culture despite a negative RADT is very low. Therefore, antibiotics should be reserved for patients with a positive RADT or throat culture, or a high index of suspicion despite a negative RADT. Overall, a study such as this should provide information that empowers clinicians to decrease the number of antibiotic prescriptions for sore throat primarily due to viral pharyngitis in order to avoid antibiotic resistance. Clinicians are encouraged to restrict antibiotic treatment for patients with confirmed GAS or highly suspicious histories and exams for bacterial pharyngitis. ■

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