Evaluation of a Rapid Method for Diagnosing Streptococcal Pharyngitis in an Office Laboratory

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Group A β-hemolytic streptococcal pharyngitis is a common problem whose accurate diagnosis depends on laboratory testing. Laboratory evaluations of rapidly done streptococcal agglutination tests available on the market indicate that the tests have acceptable specificity and sensitivity. Most such evaluative studies, however, have been performed in research settings. For example, Slifkin and Gil[1] refer to "our laboratory," the microbiology section of Allegheny General Hospital, while Fischer and Mentrup[2] apparently used laboratory technicians, and Campos and Charilaou[3] used "house staff" to collect specimens. Chang and Mohla[4] state that "all swabs were subjected to the strep test within 24–48 hours of arrival in laboratory." To be useful in the real-life office setting, the test must yield consistent, accurate results when administered by office staff under actual working conditions. The purpose of this study was to determine whether the accuracy of the Culturette Brand 10-Minute Group A Strep ID was sufficient to warrant its use as an alternative to standard throat cultures as a means of diagnosing group A β-hemolytic streptococcal pharyngitis in a primary care office under normal working conditions.

METHODS

The study was initiated in December 1985 and concluded in April 1986. Pediatric and adult patients attending the Asylum Hill Family Practice Office affiliated with the University of Connecticut Health Center and Saint Francis Hospital and Medical Center were eligible for inclusion. One hundred four consecutive patients with pharyngitis were enrolled in the study and tested for group A β-hemolytic streptococci using both the Culturette Brand 10-Minute Group A Strep ID method (Marion Scientific, Kansas City, Mo) and sheep blood agar cultures.

Duplicate specimens were obtained from each patient by swabbing the posterior pharynx and both tonsils or tonsillar fossae simultaneously with two sterile Dacron-tipped swabs as suggested by the manufacturer[5] and Campos and Charilaou.[3] One swab was streaked onto a 5 percent sheep blood agar plate (BBL-prepared media TSA 22) using the four-quadrant method. A bacitracin disc (TAXO A Disc BBL microbiology systems) was placed on the primary inoculum, and the agar was stabbed. Plates were incubated in an oxygen-limited, increased carbon dioxide environment at 37 °C for 24 to 36 hours. The other swab was used to perform the ten-minute streptococcus test according to instructions. The negative control was used each time the Culturette Brand 10-Minute Group A Strep ID was performed. Any degree of agglutination in the test circle greater than the negative control was considered positive.

Six third-year family practice residents and five nurses participated in the study. Each nurse had received two in-service training sessions from the test manufacturer. Nurses used the test for approximately one month prior to the commencement of the study to familiarize themselves with this particular agglutination reaction. Each nurse collected specimens, plated one on sheep blood agar, and completed a ten-minute test on her patients. Third-year residents interpreted the agar plates without prior knowledge of the ten-minute test results. An independent reader also interpreted the agar plates and then compared results obtained with those of the residents (blood plates) and the nurses (ten-minute test). Separate logs were kept for each of the three interpretations. If the data were inconsistent, for example, if the culture result was positive and agglutination test was negative, or vice versa, or if there was disagreement over the interpretation of the agar plate, a subculture was done at the Family Practice Center with final verification determined by the St. Francis Hospital and Medical Center Laboratory. Identification was confirmed by retesting the streptococcal isolate with Streptex reagents (Wellcome Reagents LTD).

Submitted, revised, June 9, 1987.

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TABLE 1. BLOOD AGAR AND TEN-MINUTE TEST RESULTS

Ten-Minute Test	Blood Agar Test: Positive	Blood Agar Test: Negative	Total
Positive	9	4	13
Negative	15	76	91
Total	24	80	104

RESULTS

The Culturette Brand 10-Minute Group A Strep ID test was positive for 9 of the 24 patients with positive agar plates and negative for 76 of the 80 patients with negative agar plates (Table 1). Sensitivity was 38 percent, specificity was 95 percent, positive predictive value was 69 percent, and negative predictive value was 84 percent. There were four false-positive and 15 false-negative ten-minute test results when compared with results obtained from blood agar plates or confirmatory subcultures. Three of the patients with false-positive test results were treated on the basis of the test results. The fourth was not treated because the physician elected to wait for the culture results. All 15 of the patients with false-negative results were treated on the basis of the agar plates, but otherwise would not have been treated.

To investigate differences in sensitivity of the ten-minute test in different groups of patients, the data were analyzed by sex, age, and ethnic groups. The sensitivity of the test in subjects aged less than 14 years (n = 30) was 50 percent, compared with 25 percent in subjects aged 14 years and over (n = 74). The sensitivity of the test in the 102 subjects for whom racial or ethnic data were available was 29 percent in blacks (n = 37), 70 percent in Puerto Ricans (n = 30), and 0 percent in whites (n = 35). The sensitivity of the test was 60 percent in male (n = 42) and 27 percent in female patients (n = 62).

To investigate whether the number of colonies of streptococci on the blood agar plates was associated with sensitivity of the ten-minute test, the data were stratified by colony counts. Among four plates read as positive but with ten or fewer colonies of β-hemolytic streptococci, there were two false-negative ten-minute test results (sensitivity of 50 percent). Among 20 plates read as positive with more than ten colonies per plate, there were 13 false-negative test results (sensitivity of 65 percent). These differences failed to reach statistical significance ($\chi^2 = 0.3199$, $df = 1$).

To investigate whether a particular nurse was responsible for a disproportionate share of the false-negative ten-minute tests, results were analyzed for each of the five nurses involved in the study. Nurse A performed 19 tests with

two false-negative results and one true-positive result, nurse B performed 39 tests with five false-negative results and three true-positive results, nurse C performed 23 tests with four false-negative results and three true-positive results, nurse D performed 7 tests without any false-negative results and one true-positive result, and nurse E performed 16 tests with four false-negative results and one true-positive result. The distribution of false-negative results among the nurses was not statistically significant ($\chi^2 = 3.12$, $df = 4$), although interpretation can be questioned because of the small numbers, nor did there appear to be a clinically significant clustering of false-negative ten-minute tests for only one or two nurses.

DISCUSSION

The principal finding of this study is the low sensitivity (38 percent) of the ten-minute test as compared with blood agar throat culture results in an urban family practice office setting. This low sensitivity does not appear to be related to confounding factors such as the age, sex, or ethnicity of the patient, to low colony counts, or to a particular staff member performing the test poorly. Prior reports of sensitivity of this test have ranged from 62 percent[3] to 95 percent.[1] The low sensitivity of the test in this study suggests that a negative ten-minute test result would need to be confirmed by a standard throat culture. Because 87 percent of all ten-minute tests done had negative results, nearly all patients seen would require a confirmatory throat culture. This finding reduces the advantage of the ten-minute test in terms of efficiency and cost effectiveness.

The possibility of making generalizations to other office settings based on these results is open to debate. The study practice is a residency teaching practice located in an economically disadvantaged area of Hartford, Connecticut. The nursing staff of this practice is comprised of an experienced and well-trained cadre of registered nurses and licensed practical nurses. The majority of other primary care practices in the region are similarly staffed, and in most practices the nurses, rather than certified laboratory technicians or physicians, are the ones who perform routine office-based laboratory studies. Thus, these results may well be generalizable at least to a proportion of other primary care practices in this region. Other studies have reported that agglutination tests may require experience for accurate interpretation that is beyond the abilities of office staff.[6,7] While this study was not designed to pinpoint why the sensitivity of the test is low, such research should be conducted.

These data suggest that the sensitivity of a recently marketed laboratory test is unacceptably low in a real-life office setting. This finding underscores the need for office-based practitioners to engage in quality-control procedures and to utilize audit methods such as those employed here to assure that data obtained from office diagnostic tests are sufficiently sensitive and specific to provide a solid foundation for accurate clinical decision making. It is recommended that primary care physicians who use rapid tests for streptococci testing do systematic assessments of the tests' sensitivity in their office practices by using the simple methods described here.

In conclusion, the need for a sensitive rapid test for streptococci remains. With improved sensitivity a test of this sort would have definite advantages for primary care physicians and their patients.[2,8] At present, however, it appears that the ten-minute test's low sensitivity results in the need to confirm negative findings with agar plates.

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