Original Research

Evaluation of a kit for rapid detection of group A streptococci in a pediatric emergency department

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We evaluated a kit for the rapid detection of group A streptococci from throat swabs (Culturette Brand 10-Minute Group A Strep ID, Marion Scientific, Division of Marion Laboratories, Inc., Kansas City, Missouri) in the laboratory and in a busy pediatric emergency department. The sensitivity of the kit in the laboratory was 80% for all specimens and 94% for specimens with more than 10 colony-forming units of group A streptococci; the specificity was 99%. After initial training, emergency department pediatricians and nurses achieved sensitivities of 72% and 69% respectively. The specificity achieved by the pediatricians was 76% initially but 96% after further training. Untrained residents achieved a sensitivity of 58%. We conclude that this kit is potentially useful in the hands of adequately trained personnel, but without training the accuracy of the results is unacceptable. We recommend that the kit be used by designated staff trained and monitored by laboratory personnel.

Au laboratoire et dans un service d'urgences pédiatriques fort achalandé, nous avons fait l'essai d'une trousse pour la recherche rapide (en 10 minutes) des streptocoques du groupe A dans les écouvillons de gorge (Culturette Brand 10-Minute Group A Strep ID, Marion Scientific, partie de Marion Laboratories Inc., Kansas City, Missouri). Au laboratoire nous obtenons un taux de sensibilité de 80% pour l'ensemble des échantillons et de 94% pour ceux qui donneront plus de 10 colonies de ces bactéries; la spécificité est de 99%. Après une formation à cet effet, les pédiatres et les infirmières du service d'urgences atteignent des sensibilités respectives de 72% et 69%. La spécificité pour les pédiatres, qui est d'abord de 76%, atteint 96% après un supplément de formation. Les résidents sans formation préalable n'atteignent qu'une sensibilité de 58%. Nous concluons que si cette trousse pourrait être utile dans les mains de personnes ayant subi une formation à cet effet, sans celle-ci elle ne donne pas de résultats suffisamment précis. Nous en recommandons l'usage par des personnes formées sous la surveillance du personnel du laboratoire.

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Pediatricians and staff of hospital emergency departments see many children who have pharyngitis. The decision to give an antibiotic depends on distinguishing between bacterial and viral pharyngitis by examining a throat swab for the presence of group A β-hemolytic streptococci. Kits that involve an immunologic method to detect the presence of group A streptococcal antigen have become available in the last few years. The kits provide a rapid result, and the sensitivity and specificity are high when the tests are performed in a laboratory,[1-6] but less attention has been paid to the performance of the tests outside the laboratory by relatively untrained personnel.

We carried out a trial to determine the sensitivity and specificity of a rapid test kit in a busy pediatric emergency department.

Methods

The study was divided into three parts. In part 1 all throat swabs received in the laboratory between March and April 1984 were plated onto 5% sheep blood agar, which was then incubated anaerobically. Group A streptococci were identified by colonial appearance and confirmed by means of fluorescent antibody staining or coagglutination. After plating, the swab was tested with the Culturette Brand 10-Minute Group A Strep ID kit (Marion Scientific, Division of Marion Laboratories, Inc., Kansas City, Missouri) according to the

manufacturer's instructions by two trained senior members of the laboratory staff.

In part 2 the manufacturer's representative instructed 5 pediatricians and 18 nurses in the emergency department in the use of the kit. Patients who presented with pharyngitis between March and August 1985 were entered into the study at the discretion of the pediatricians. A rayon-tipped double swab was used to obtain throat swabs. One swab was sent to the laboratory for culture, and the other was tested with the kit in the emergency department.

In part 3, carried out between November 1985 and February 1986, one of us (F.T.H.C.) gave the five emergency department pediatricians additional instruction. The 19 residents rotating through the emergency department were requested to use the kit when appropriate according to the manufacturer's directions on the package insert; they received no further instruction.

Throughout the study the rapid test was completed and the results were reported before the culture result was available, and the staff who read and reported the culture results were not aware of the kit results.

Results

Table I shows the sensitivity and specificity of the kit when used by the laboratory and emergency department staff. The overall sensitivity in the hands of laboratory staff was 80%; when the results for specimens with 10 or fewer colony-forming units of group A streptococci were excluded, the sensitivity was 94%. The specificity was 99%.

When the rapid test was performed by emergency department staff after initial training the sensitivity was 72% for the pediatricians and 69% for the nurses, results that were not significantly different from those obtained by the laboratory staff. The nurses achieved a higher specificity than the pediatricians (93% v. 76%). After further instruction the pediatricians achieved a sensitivity of 77% and a specificity of 96%.

The residents achieved a sensitivity of 58% and a negative predictive value of 74%, values significantly different from those for the laboratory staff ($p < 0.05$, chi-squared test).

Discussion

The results obtained in our study by the laboratory staff were in accordance with those reported by other workers in similar trials[3-6] and indicate that technically the test is potentially useful. Review of the charts of the four patients for whom the test results were false-positive in this part of the study indicated that at least one of the patients may have had group A streptococcal antigen in the nasopharynx in the absence of viable organisms. The patient had well-documented scarlet fever and had received penicillin before the specimen was taken. The performance of the test by the nurses with initial training and the fully trained pediatricians did not differ significantly from that of the laboratory staff, but the sensitivity and negative predictive values achieved by the untrained residents differed significantly from those achieved by the laboratory staff.

In a trial in a pediatric office a sensitivity of 93.4% and a specificity of 98.2% were obtained, but the authors pointed out that since the same person read both the kit results and the culture plates the evaluation may have been biased.[7] Sensitivities of 83% and 77% and specificities of 99% and 98% were obtained in two office studies in which those who read the culture plates were unaware of the kit results.[8,9] In a study in an emergency department a very low sensitivity, 44%, was achieved, even though the test was performed by laboratory personnel.[10] The authors speculated

Table I — Results of testing with a kit for the rapid detection of group A streptococci from throat swabs in a pediatric emergency department

	Result; no. of specimens				%				
	Culture-positive		Culture-negative						
Personnel	+	−	−	+	Sensitivity	Specificity	Positive predictive value	Negative predictive value	Prevalence rate
Laboratory staff (n = 2)									
All specimens	33/41	8/41	263/267	4/267	80	99	89	97	13
Specimens with > 10 colony-forming units	33/35	2/35	263/267	4/267	94	99	89	99	12
Emergency department staff									
Pediatricians (n = 5)									
After initial training	13/18	5/18	32/42	10/42	72	76	57	86	30
After further training	13/17	4/17	25/26	1/26	77	96	93	86	40
Nurses (after initial training) (n = 18)	25/36	11/36	74/80	6/80	69	93	81	87	31
Residents (untrained) (n = 19)	23/40	17/40	48/52	4/52	58	92	85	74	43

that this result may have been due to the presence in their population of large numbers of patients with small numbers of streptococci in their throats. In another study from an emergency department a sensitivity of 78% and a specificity of 93% were obtained.[11] Two kits were used, including the one used in our study, but the authors did not state who did the tests or whether the trial was blinded. In a recent study in Canada in which the tests were done in the laboratory the sensitivity was 95% and the specificity 98% for specimens having more than 10 colony-forming units.[12]

Our results show that nonlaboratory staff can achieve a specificity and sensitivity with the rapid test kit comparable to those of laboratory staff but that adequate training is necessary. The training should include emphasis on the necessity for controls and strict adherence to the manufacturer's instructions in interpretation. After initial training the specificity achieved by the pediatricians was lower than that for the nurses. The pediatricians may have overread the latex agglutination reaction because of a clinically based desire to establish a bacterial cause. After preliminary training the specificity obtained by the pediatricians improved.

The economics and merits of office testing have been the subject of much debate,[13,14] and the criteria by which new tests should be evaluated have been well defined.[15] A distinction must be made between biochemical tests that give a quantitative measurement and tests that give a Yes/No result, such as the one that we evaluated. Some loss of precision in a measurement may, under some circumstances, be an acceptable price to pay for convenience and rapidity, provided that there is adequate quality control and that limits of acceptable performance have been defined. The individual patient, however, is not well served by a wrong result in a Yes/No test, and it is therefore reasonable to demand a high sensitivity and specificity wherever the test is being done and whoever is doing it. It is also relevant to consider the circumstances in which the test is to be used. The low negative predictive value obtained by the residents in our study reflects both reduced sensitivity and a high prevalence of group A streptococcal infection in the patients selected by this group for testing. If the test kit is to be used only for patients with obvious symptoms, among whom the prevalence of the disease is high, the value of the test is reduced unless an adequate sensitivity is achieved.

Culture remains the definitive method for the diagnosis of group A streptococcal pharyngitis, and the use of a rapid test kit is a compromise in which a small loss of accuracy is offset by rapidity, convenience or economy. Use of a kit implies acceptance of failure to detect small numbers of organisms. It also has to be recognized that even at a high sensitivity the occasional specimen with substantial numbers of organisms may fail to give a positive result. The rarity of poststreptococcal complications in North America may justify acceptance of these limitations, but the incidence of rheumatic fever is increasing in some parts of the continent,[16] and if this trend continues the entire issue of diagnosis and management of pharyngitis may need to be re-examined.

Our results, considered with those of other workers,[3-12] indicate that if a decision is made to use such kits in hospitals or offices, testing should be assigned to designated staff trained and monitored by laboratory personnel. In hospital, formal certification of competence to perform a delegated medical act could be required. We feel that unrestricted availability of kits like the one we evaluated, such that they are used without adequate training and without adequate quality control, will not promote good patient care.

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