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How Reliable and Useful Is the Latex Agglutination Test in Diagnosing Streptococcal Throat Infection in General Practice?

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A rapid latex agglutination test for diagnosing streptococcal pharyngitis in general practice was evaluated on 226 patients with acute throat infection. The test had a sensitivity of 96 % and a specificity of 91 % regarding group A beta hemolytic streptococci. The test was fairly simple to perform and the result was available before the patient left the office. The test was supplied as a self-contained kit, was safe to handle and economically acceptable. Even though this test is not as reliable as the traditional microbiological culture, it represents a significant practical and clinical improvement in the daily management of patients with acute throat infections.

Key words: throat infection, streptococcal pharyngitis, latex agglutination tests, office microbiology, primary health care.

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Throat infection is a problem frequently encountered in primary medical care. Less than half of such infections is caused by beta haemolytic streptococci (1). Recent controlled studies have shown that antibiotics significantly shorten the duration of streptococcal pharyngitis while not influencing the clinical course of non-streptococcal pharyngitis (2, 3). Early specific diagnosis and correct treatment may limit the risk of cross infections in families, nursing homes or schools (4). Antibiotics reduce the risk of the suppurative complications of streptococcal pharyngitis, and have been claimed to reduce the incidence of the uncommon, but serious non-infectious sequelae of gr. A streptococci, such as rheumatic fever and glomerulonephritis (5).

The nonspecific nature of signs and symptoms of streptococcal pharyngitis makes the clinical diagnosis difficult. An accurate diagnosis has until recently been based on bacteriological confirmation by throat culture. The inherent delay of one or two days in throat culturing has, however, led many physicians to disregard the need for this microbiological confirmation (6). New diagnostic tests detecting beta hemolytic streptococci directly from throat swabs have recently become available. Evaluation of these antigen detection kits performed at microbiological laboratories indicates that they have an acceptable sensitivity and specificity (7). Few evaluations have, however, been done to see if these "simple" tests work outside the laboratory as well (4, 8).

The aim of the present study was to evaluate the reliability and practicality of the streptococcal latex agglutination test as performed in primary care.

MATERIAL AND METHODS

The study was carried out at seven health centres in the City of Oslo between November 1985 and March 1986. Patients with symptoms or signs indicating acute throat infection were eligible. Patients were not included if signs or symptoms had lasted more than five days, if they had used antibiotics the previous seven days or used antiseptic mouthwash

Table I. *Microbiological throat cultures from 226 patients with accute throat infection*

Beta hemolytic streptococci		86
Group A	51	
Group B	7	
Group C	15	
Group G	6	
S. milleri (group F or non-groupable)	6	
Not further identified	1	
Non-beta hemolytic streptococci		140
Total		226

or throat lozengers during the past 12 hours. Patients were also excluded if there were difficulties obtaining throat swabs according to protocol.

Patients were first examined by a physician making a clinical diagnosis of *either* streptococcal *or* non-streptococcal throat infection. Throat specimens were taken by firmly rubbing tonsils and pharynx posterior with two cotton swabs placed side by side. One cotton swab was used for streptococcal gr. A and gr. C antigen detection at the office laboratory. The other swab was placed on a transport medium (a modification of *Stuart medium*, National Institute of Public Health, Oslo, Norway) and sent to the Microbiological Laboratory at Ullevaal University Hospital, Oslo, within 24 hours.

Office laboratory procedure

The immunological detection of gr. A or C streptococci was performed using the commercially available test-kit PathoDx Strep A (Diagnostic Products Corporation, California, USA), following the manufacturer's recommended test procedure. The specimen swab was processed at the office laboratory within six hours. Making house-calls, one of the double throat swabs was immediately placed in the transport medium, letting the other air-dry while bringing it back to the office for analysis.

The time from when the throat swabs were taken until the test results were available ("diagnostic delay" time) and the time used from beginning the laboratory procedure until results were available ("hands-on" time) were recorded. The examining doctor's clinical diagnosis was unknown to the laboratory personnel. Positive and negative controls were performed daily at each laboratory. The office laboratories at the participating health centres are run by nurses. In order to obtain a more uniform test procedure the nurses and doctors took part in a brief introductory meeting and demonstration at the onset of the study.

Microbiological laboratory procedure

One throat swab was streaked on two sheep blood agar plates (5%) which were incubated for 18 to 24 hours at 37°C respectively in an atmosphere with 5% CO_2 or under anaerobic conditions. The plates were examined for beta hemolytic colonies. Gram positive, catalase negative, hemolytic colonies were subcultured for further identification using serological grouping (coagglutination, gr. A, B, C, F, G) and biochemical methods. The microbiological laboratory personnel were neither informed about the clinical diagnosis nor the results of the latex agglutination test.

Evaluation of clinical usefulness

At the end of the study the participating doctors were interviewed by questionnaire regarding the applicability and clinical usefulness of the latex agglutination test. The staff nurses evaluated the practical implications and technical aspects of the test procedure, comparing it to that of the erythrocyte sedimentation rate (ESR).

RESULTS

Twenty-four doctors included 235 patients. Nine patients were excluded due to protocol violations, leaving 226 patients for further evaluation. Eight of these tests were taken during house-calls. Gr. A streptococci were isolated by throat culture from 51 of the patients and gr. C from 15 patients (Table I). Forty-nine patients had gr. A positive throat culture and positive gr. A agglutination test, resulting in a test sensitivity of (49/51) 96% regarding gr. A streptococci (Table II). The corresponding value of gr. C sensitivity was (13/15) 87%. The combined sensitivity of gr. A and gr. C was 94% (62/66). Of the 160 patients with gr. A or C negative culture 144 had negative agglutination test, giving a specificity of 90%. The gr. A test alone had a specificity of 91% (146/160). Positive predictive value for gr. A and C was 78% (62/80) and negative predictive value 99% (144/146).

The participating doctors' evaluation of the usefulness of the latex agglutination test in addition to their overall clinical assessment in diagnosing the etiology of acute throat infections is shown in Table

Table II. *Latex agglutination test compared with throat culture, from 226 patients with acute throat infection*

	Throat culture			
	Beta hemolytic streptococci		Non-beta hemolytic	
Agglutination test	Gr. A	Gr. C	streptococci	Total
Gr. A	49	1	14	64
Gr. C	1	13	2	16
Negative	1	1	144	146
Total	51	15	160	226

III. Eighteen of the twenty-four doctors (75%) rated the clinical usefulness of the latex agglutination test to be between seven and ten. Sixteen of the doctors stated they would continue to use the test regularly also after the study period was finished, the remainders would use it occasionally. The median "diagnostic delay" time was 13 min (range 6–239 min), median "hands-on" time was nine minutes (range 5–30 min). Fifteen of the twenty nurses found the agglutination test somewhat more work consuming than the ESR, while five found it considerably more work consuming. One nurse rated the technical complexity of the agglutination test equal to that of ESR, 14 found it somewhat more complex and five nurses found it considerably more complex to perform than the ESR. Six of the twenty nurses expressed difficulties in interpreting weak endpoints of the agglutination test.

DISCUSSION

Commercially available tests which permit rapid laboratory-confirmed diagnosis of streptococcal pharyngitis have recently been studied (7). None were found to be distinctly superior or inferior. The accuracy of the different agglutination tests were reported to be within the same range. The cost of each was compatible. Time to complete the test varied between six and seventy minutes. In the present study PathoDx-StrepA was selected for clinical evaluation as this test was reported to have a short completion time, to detect both gr. A and C streptococci and to be supplied in self-contained kits. In the present study the gr. A test sensitivity was found to be 96%, gr. C sensitivity 87% and the combined sensitivity of gr. A or gr. C 94%. This is within the upper range of values reported in other studies (9). The specificity of the gr. A test was 91%. Most other studies quote specificities above 95% (9). The somewhat lower specificity found in this study is probably not due to the test kit itself, but rather to the lower level of precision caused by a new test procedure tried at different office laboratories. Reading the agglutination test is subjective; strong agglutination is easy to read while weak reactions are difficult to evaluate. When in doubt of the end point some of the nurses recorded the result as weak positive. Kellogg & Manzella reported in 1986 that their laboratory technologist trained in the test procedure only by the manufacturer's representative had a false-positive rate of 10% (10). After additional training by qualified laboratory personnel, the false-positive rate dropped to less than one percent.

There are difficulties using the throat culture as "gold standard". Throat cultures are known to have a 10% false-negative rate even when properly performed (10). Bacteria might also die during transport. Some "false-positive" agglutination tests may in fact have been true-positive. Another diagnostic problem is the occurrence of *S. milleri* in throat cultures. This streptococcus can occur with beta hemolysis and the antigens of the gr. A, C, F or G or be non-groupable (11). *S. milleri* is considered to be without pathogenic role in acute tonsilli-

Table III. *The clinical usefulness of PathoDx, as evaluated by 24 general practitioners, using a visual analogue scale*

	No use										Considerable use
	0	1	2	3	4	5	6	7	8	9	10
Rate of answers in per cent						8	17	25	17	29	4

tis (12). In our study five of the gr. A streptococci and all of the gr. C streptococci were biochemically identified as *S. milleri*. This introduces an overdiagnosis of streptococcal pharyngitis needing antibacterial treatment, especially regarding infections caused by gr. C streptococci. The usefulness of the C antigen detection in the rapid office test may thus be questionable.

Most doctors participating in this clinical study were at the onset reluctant to the introduction of a new office laboratory procedure. At the end of the five-month study period no doctors remained negative to the test, 18 of the 24 even expressed that the test provided good or excellent help in their overall assessment of patients with throat infections.

ESR is performed in one quarter of all Norwegian general practitioners' consultations. Fifteen (75%) of the nurses found the new latex agglutination test only somewhat more technically complex and work consuming than the established routine of the ESR. The median "hands on" time performing the latex test was nine minutes. The cost of the described test kit is in Norway presently equal to that of commercially available office culture-plates. The cost of culturing a throat swab at a microbiological laboratory is three to four times as high. The micronitrous acid extraction step in the test procedure destroyed the viability of bacterial pathogens, used test material could be discarded without potential biohazard (13).

In conclusion, we found PathoDx-Strep A to be a reliable test representing a practical and clinical improvement in the daily management of patients with acute throat infections in general practice.

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