Use of Wellcogen Group B Streptococcal Latex Fixation Test to Detect Group B Streptococcus in Amniotic Fluid

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The latex fixation test for rapid detection of microbiologic agents has been in use for several years to detect pathogens from such sources as the nasopharynx, cerebral spinal fluid, and urine.[1,2] Compared with cultures, the latex fixation test has the advantage of being fairly rapid, and even though the test has mixed sensitivities and specificities, depending on the pathogen, it is generally viewed as a good screening method when time is important.[3,4]

Speed is essential in diagnosing group B streptococcal infection in the neonate. This potentially life-threatening infection has a poor prognosis, and early recognition and treatment of the streptococcal infection may influence the outcome of the disease. Historically, the most important source for group B streptococcal infection has been maternal chorioamnionitis, and examining the amniotic fluid for early detection of group B streptococci in patients at risk should be more efficacious than culturing the neonate.

Although a strong case can be made for use of a rapid screening method for amniotic fluid, such as the latex fixation test, using such a test is not the normal practice. A review of current literature failed to reveal any studies demonstrating the efficacy of using the latex fixation test to detect group B streptococcus in amniotic fluid.

The latex fixation test for detection of group B streptococci has been studied for other body fluids and was found to have a sensitivity of 84 percent and a specificity of 94 percent for urine, a sensitivity of 64 percent and a specificity of 100 percent when used to test cerebral spinal fluid, and a sensitivity of 68 percent and a specificity of 100 percent for serum, based on a manufacturer's product information.[5] The manufacturer also addresses the problem of inappropriate (nonspecific) agglutination on the negative control slide. When this nonspecific agglutination occurs, the entire result must be considered "inconclusive," and the test slide cannot be interpreted.

A study by Smith et al[6] has addressed the use of latex fixation and the problem of inconclusive results when used on amniotic fluid. In this study 63 percent of urine samples, 4 percent of cerebral spinal fluid samples, 29 percent of serum samples, and 41 percent of amniotic fluid samples were found to have nonspecific agglutination of the negative control slide on the Wellcogen Strep-B* streptococcal latex fixation test.

Because preexisting data have not addressed sensitivity and specificity on clinical samples, the current study was designed to test the efficacy of using the Wellcogen Strep-B streptococcal latex fixation test on amniotic fluid to detect group B streptococcus, using culture results as the standard. The study also was designed to detect any limitations that might be imposed by nonspecific agglutination in the negative control slide.

METHODS

Amniotic fluid specimens were submitted from patients being followed on the obstetrical service at Madigan Army Medical Center, Tacoma, Washington. The majority of these patients were being evaluated during labor, although some specimens came from elective amniocentesis prior to onset of labor. All specimens were submitted because of a clinical suspicion of chorioamnionitis at the time of evaluation. These specimens were then sent to the Department of Microbiology at Madigan Medical Center for culture and testing with the Wellcogen Strep-B test; none

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was excluded. A total of 118 specimens from 114 patients were submitted during the eight-month study period, with five specimens being obtained through amniocentesis and the remainder being obtained through intrauterine pressure catheter or from a vaginal pool sample after rupture of the membranes.

Upon receipt of the specimen, the Department of Microbiology first would remove a portion of the amniotic fluid from its sterile container and plate it on standard sheep blood agar, chocolate agar, MacConkey agar, and in thioglycolate broth. These cultures were observed for 48 hours and then discarded if no growth appeared. For the purpose of this study, a positive culture refers to one from which β-hemolytic group B streptococci were isolated, and a negative culture as one from which group B streptococci were not isolated, even if other organisms were isolated.

After culturing, the specimen was then tested with the Wellcogen Strep-B kit in accordance with the manufacturer's recommended protocol.[5] A key point in the test protocol occurs when the technician adds amniotic fluid supernatant to the test circle and the negative control circle. After a period of observation, the negative control circle should have no agglutination. If nonspecific agglutination was present in the control circle, then the test was reported as inconclusive. Otherwise, the test was reported as either positive or negative, depending on the presence or absence of agglutination in the test circle.

RESULTS

A total of ten specimens tested positive for group B streptococci using the Wellcogen Strep-B latex fixation method (Table 1). Of these ten, only five were also positive by culture. A total of 118 specimens were submitted and tested, but a high incidence of nonspecific agglutination on the negative control circle resulted in 44 inconclusive tests to use in assessing the efficacy of the latex fixation method. No false-negative and five false-positive results occurred when only this conclusive test group was considered, which gives the latex fixation test for the conclusive samples a sensitivity of 100 percent and a specificity of 92.7 percent ($P < .001$).

In considering the predictive value of this test, that is, the likelihood that an amniotic fluid sample that tested positive for group B streptococci by latex fixation actually has the organism, it would be useful to know the true prevalence of group B streptococci as a pathogen in amniotic fluid. The predictive value equals prevalence × sensitivity/(1 − specificity), and because this prevalence is unknown, an estimate of the predictive value of a positive test result could be made by using the true-positive results divided by the true-positive results plus the false-positive results, or 5 divided by (5 + 5), or 50 percent.

TABLE 1. LATEX FIXATION TESTS FOR GROUP B STREPTOCOCCUS COMPARED WITH THE STANDARD OF CULTURE

Results	Culture Result		
	Positive	Negative	Total
Latex fixation			
Positive	5 (TP)	5 (FP)	10
Negative	0 (FN)	64 (TN)	64
Specimens with conclusive results	5	69	74
Specimen with inconclusive results	5	39	44
Actual total, conclusive and inconclusive	10	108	118

TP—true positive, FP—false positive, FN—false negative, TN—true negative

DISCUSSION

The absence of data in the medical literature concerning the use of the latex fixation test for group B streptococci in amniotic fluid was a strong motivating factor in undertaking this study. The data presented herein demonstrate that the Wellcogen Strep-B kit can be utilized as a rapid screening test for group B streptococcus in amniotic fluid, but only if the negative control panel is truly negative and not "inconclusive." Because of the high number of inconclusive results demonstrated by this study, several samples with culture-proven group B streptococci could not be utilized in determining the sensitivity and specificity of the test, and the sensitivity and specificity of 100 and 92 percent, respectively, may be misleading with such a small sample. A larger study is planned that will not only attempt to validate the data from this study, but will assess different methods of processing amniotic fluid specimens for decreasing the number of inconclusive results.

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