Evaluation of a Rapid Screening Test for Detecting Group B Streptococci in Pregnant Women

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The QUIDEL Group B Strep Test is an enzyme immunoassay (EIA) that was compared with culture for the rapid detection of moderate to high levels of group B streptococci (GBS) colonization in pregnant women. A total of 331 pregnant women were included in the study protocol, and GBS were cultured from 19 of these patients in moderate or greater amounts (incidence of 5.7%). Compared with culture, the EIA had a sensitivity, specificity, and positive and negative predictive values of 89, 99, 89, and 99%, respectively. With a sensitivity of 89%, the 95% confidence interval for this assay is 88 to 90%. The QUIDEL EIA test can be performed in less than 10 min and appears to be a reliable method for detecting moderate or greater amounts of GBS in vaginal or cervical specimens.

Group B streptococci (GBS) are an important cause of neonatal sepsis in the United States, with over 12,000 reported cases annually and a mortality rate of 20 to 30% (8). The reservoir for the transmission of GBS to the newborn is the birth canal, where colonization rates range from 5 to 30% in pregnant women (6). Importantly, over 80% of systemic GBS infections occur in premature infants, with the primary risk factors being prolonged labor or the premature rupture of membranes (2, 3, 13, 15).

Antepartum culture of the birth canal has been used to identify pregnant women colonized with GBS. However, subsequent treatment of antepartum patients having positive cultures has not been cost-effective, and recolonization is common (1, 16). In recent years, several studies have shown that the intrapartum treatment of GBS-colonized women significantly reduces the incidence and mortality associated with neonatal GBS sepsis (4, 10–12, 18). As such, GBS screening cultures are more useful when performed on intrapartum women who present with risk factors associated with the development of GBS infection. Unfortunately, delaying GBS surveillance cultures until the patient is in labor is not a satisfactory solution to the problem because culture results usually are not available soon enough to identify patients who are candidates for receiving intrapartum chemoprophylaxis.

For these reasons, efforts have been made to develop a rapid and reliable test to identify GBS colonization in women in early labor. The purpose of this study is to compare the performance of a rapid enzyme immunoassay (EIA), called the QUIDEL Group B Strep Test (QUIDEL, San Diego, Calif.), with culture for the detection of GBS directly in vaginal and cervical samples.

Solid-shaft, rayon-tipped swabs were used to collect cervical or vaginal specimens from women in their first or third trimester of pregnancy. Specimens were transported to the laboratory by the Culturette Collection and Transport System (Becton Dickinson Microbiology Systems, Cockeysville, Md.). Each swab sample was first inoculated onto a plate containing 5% sheep blood agar, chocolate agar, MacConkey agar, and NYC agar, smeared on a slide for Gram stain, and then assayed for GBS by the EIA. Culture plates were incubated for 48 h and examined daily for the presence of bacterial growth. All GBS isolates were confirmed by Strep-tex (Wellcome Diagnostics, Research Triangle Park, N.C.), and the number of GBS colonies recovered per plate was semiquantitatively as follows: low (<10 colonies), moderate (10 to 50 colonies), and high (>50 colonies).

The QUIDEL Group B Strep Test was performed in accordance with the manufacturer's instructions. The system consists of a QUIDEL test cartridge that contains a filtration membrane coated with rabbit polyclonal antibodies to GBS. First, vaginal or cervical swab samples are extracted with extraction reagents provided by the manufacturer. The patient-extracted fluid sample is then transferred to the test cartridge and gravity filtered through the membrane. If GBS antigen is present in the sample, it will bind to the antibodies on the surface of the membrane. A reagent containing polyclonal anti-group B streptococcus antibody-enzyme conjugate is then added to the test cartridge and allowed to incubate at room temperature for 1 min. A specific antibody-antigen (antibody-enzyme) complex will form on the membrane in the presence of GBS. Following rinsing of the membrane with a wash solution to remove any unbound antibody-enzyme conjugate, an enzyme substrate solution is added to the test cartridge and allowed to react for 2 min.

If GBS is present in the patient sample, a solid blue circle will appear on the test cartridge membrane, indicating a positive result. If GBS is not present in the sample, a blue negative sign with no blue circle will appear on the membrane. A positive GBS control (which was included in the kit) was performed with each test assay. The entire EIA (from specimen extraction to interpretation of results) can be performed in less than 10 min.

The cultural recovery of GBS in moderate or greater amounts was the interpretative criterion used in determining whether a patient had GBS infection. An important aspect of this EIA is that it is not designed to detect low levels (less
than 10 colonies per plate) of GBS because the manufacturer believes that low levels of GBS colonization do not constitute a significant risk factor for the development of neonatal infection. Accordingly, specimen cultures that grew low numbers of GBS were regarded as negative on the basis of these guidelines. Standard methods (14) were used to calculate the statistical parameters of sensitivity, specificity, and positive and negative predictive values.

A total of 333 vaginal or cervical samples were processed in this study. Two samples were excluded from the study group because one specimen clogged the test cartridge membrane filter and the other gave an uninterpretable result. Both of these samples gave negative cultural results for GBS. Of the remaining 331 specimens, GBS were recovered from culture in moderate or greater amounts from 19 specimens for an overall disease prevalence of 5.7%. Of the 312 specimens that were regarded as negative by culture, 4 actually grew low numbers of GBS. On the basis of the study guidelines, however, these cultures were regarded as negative and they also gave negative EIA results. Only two false-negative and two false-negative EIA results were observed. Of the two false-negative EIA samples, both grew moderate numbers of GBS on culture. Compared with culture, the EIA had a sensitivity, specificity, and positive and negative predictive values of 89, 99, 89, and 99%, respectively. The overall test correlation of EIA with culture was 98.8%.

The vertical transmission of GBS can be successfully interrupted by the prophylactic administration of ampicillin to all women in labor (3, 18). However, the indiscriminate chemoprophylaxis of these women prior to delivery is neither practical nor necessary. Even though the incidence of neonatal GBS disease may be reduced by this practice, the risk of developing antibacterial resistance, adverse maternal and/or fetal drug reactions, and other complications outweighs the benefits of such chemoprophylactic measures (12).

Routine culture has been the traditional method of identifying GBS-colonized patients. However, as mentioned previously, conventional culture is a time-consuming process in which results are not usually available for 24 to 72 h. Therefore, routine culture is not a practical solution to the problem of identifying colonized patients as candidates for chemoprophylaxis.

As an alternative to routine culture, several more rapid methods, such as the use of selective-enrichment broth (10, 12), latex agglutination assay (5, 9, 12), and Gram stained smear (7, 17), have been developed and/or evaluated for selectively screening intrapartum mothers for GBS colonization. The use of any of these tests significantly reduces the time period for the availability of the final report compared with using routine culture. Unfortunately, none of the tests have sufficient sensitivity and/or specificity to assure the accuracy of their results (5, 7, 9, 10, 12, 17). More recently, an EIA called Equate (Binax, South Portland, Maine) has been developed for the rapid detection of GBS directly in clinical specimens. However, the sensitivity of this system was only 60% compared with that of culture (17).

The results of our study indicate that the QUIDEL Group B Strept Test is a reliable method for identifying women who are colonized with moderate or greater amounts of GBS. Importantly, only two false-negative EIA results were observed in this study, and there were moderate numbers of GBS grown on the two corresponding cultures. Because only one swab was used to inoculate four culture media, to prepare a smear for Gram stain, and then to perform the EIA test, the two false-negative EIA results could represent a bias in favor of culture because of the order in which the tests were performed.

A possible limitation of the EIA is that it is not designed to detect low levels of GBS colonization. Although neonatal infections can occur in mothers with low amounts of GBS colonization, most investigators believe that the risk is very small and that most neonatal infections develop from heavily colonized mothers (17).

Despite this potential limitation, the QUIDEL Group B Strept Test appears to be a reliable alternative to culture for the rapid detection of GBS in cervical or vaginal samples. Importantly, the entire test can be performed in less than 10 min so that reliable results can be made available to the physician in a time period that is commensurate with the needs of clinical practice.

REFERENCES