Infectious Diseases in Obstetrics and Gynecology 7:202–205 (1999)


# Evaluation of the Strep B OIA Test Compared to Standard Culture Methods for Detection of Group B Streptococci

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ABSTRACT

*Objective:* This study evaluated the accuracy of the commercial product Strep B OIA (optical immunoassay) compared to the standard agar and broth culture methods for detecting vaginal colonization with group B streptococcus (GBS).

*Methods:* Preoperative vaginal cultures were obtained from 141 nonpregnant gynecological patients undergoing major gynecologic surgery. Major gynecologic surgery was defined as benign gynecologic, gyne-oncology, and urogynecologic procedures. The results of the Strep B OIA test were compared to the results obtained from SXT agar (selective for GBS), colistin-nalidixic acid (CNA) agar, and Todd-Hewitt broth cultures.

*Results:* The prevalence of vaginal GBS colonization in this population was 20.6%. The sample sensitivity and specificity of the OIA method were 58.6% and 85.7%, respectively. These values are lower than the sensitivity and specificity of 85.4% and 91.5%, respectively, given in the OIA package insert. Although the sample negative predictive value was fairly high (88.9%), the positive predictive value was low (51.5%).

*Conclusion:* Although a previous study stated that the product Strep B OIA reduces the time required to obtain results (30 minutes versus days) and can, therefore, function as a useful diagnostic tool in the management of early-onset GBS disease, the present study's finding of low sensitivity and low positive predictive value indicates that this test may have very limited clinical value. Infect. Dis. Obstet. Gynecol. 7:202–205, 1999. © 1999 Wiley-Liss, Inc.

## INTRODUCTION

Group B streptococcus (GBS) has been identified as an important and lethal pathogen in the bacterial disease of the newborn and is the leading cause of neonatal sepsis and meningitis in the United States.[1–3] The GBS infection rate is approximately one to three per 1000 live births and carries with it a mortality rate of 20%.[3,4] Despite adequate numbers of clinical trials that demonstrate the effectiveness of intrapartum antibiotic prophylaxis, the incidence of neonatal GBS disease has remained unchanged due to inconsistent prevention strategies.[5]

Colonization with GBS is common among pregnant women, with an incidence of 15% to 40%.[3,6] Because GBS carriage in the reproductive tract of pregnant women is intermittent and may be transient, the intensity and presence of intrapartum GBS colonization are the key factors involved in vertical transmission to the infant.[3,7] Vertical transmission rates range from 30% to 70% of culture-positive women to neonates, but only 1% to 2% of these neonates go on to develop GBS disease.[8] The risk of neonatal infection rises when certain risk factors are present. These risk factors include: premature rupture of membranes, preterm labor,

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Clinical Study

Received 15 December 1998
Accepted 9 June 1999

prolonged rupture of membranes, a previously-GBS-affected sibling, heavy maternal GBS colonization, and maternal fever during labor.[3]

The standard method for GBS detection is a broth culture obtained from vaginal and rectal swab specimens. The specimens are stored and transported in a compact medium until they can be processed and cultured. The standard culture method is both sensitive and specific, but because this procedure employs primary incubation in a selective broth for an 18–24-hour period, multiple rapid GBS detection tests have been developed throughout the years. The Optical ImmunoAssay (OIA) test, developed by BioStar, Inc. (Boulder, CO) is a novel immunoassay that utilizes thin-film interference effects to confirm the presence of a carbohydrate antigen unique to GBS, complexed with an antibody on a solid surface.[9,10] The resulting change in the thickness of the immune complex alters the optical path of light and changes the perception of color to the naked eye. The presence of the specific GBS antigen yields a deep purple color. The absence of the antigen results in no change, and the test surface remains gold.[10]

The purpose of this study was to investigate the accuracy of the Strep B OIA test, compared to the standard culture method for detecting vaginal colonization with GBS.

## MATERIALS AND METHODS

A total of 141 patients participated in this study. Vaginal cultures were obtained preoperatively from nonpregnant gynecologic patients undergoing major gynecological surgery, which comprised benign gynecologic surgery, gynecologic oncology surgery, and urogynecologic surgery. All of the patients presented to Rush-Presbyterian-St. Luke's Medical Center (Chicago, IL) during the months of July and August 1997. Patients were identified only by a code number in order to insure confidentiality.

Two vaginal specimens were obtained from each patient. The specimens were collected in a uniform manner with two sterile cotton-tipped applicators. The swabs were rubbed against the vaginal cavity wall in the distal one-third of the vagina, and a circular motion was used as the swabs were removed. The swabs were then placed in Culturette II brand transport medium (Remel, Lenexa, KS), and were mixed equally between the pledget and the swabs by external compression on the transport tube. The specimens were then delivered to the laboratory at ambient temperature for analysis. The processing of the specimens was performed within one hour of collection.

One of the vaginal swabs was processed directly with the Strep B OIA test from BioStar, obtaining results in approximately 30 minutes. The other swab was streaked directly onto selective media, with either colistin-nalidixic acid (CNA) or sulfamethoxazole-trimethoprim (SXT) agar, and incubated aerobically at 37° C for 24 hours. Care was taken to rotate the swab so that all sides would be exposed to the agar. Each plate was streaked in such a manner as to allow estimation of the density of growth of the organisms. The swab not used for the Strep B OIA test was also placed in Todd-Hewitt broth containing 5% sheep red blood cells, gentamycin (8 g/ml), and nalidixic acid (15 g/ml) and incubated for 24 hours at 37° C. The results from the Strep B OIA test and the standard cultures were obtained in a blind fashion; i.e., the interpretation of test results for a patient was made without knowledge of the results of the other tests.

After overnight incubation, the primary plates were examined for growth of beta-hemolytic colonies and non-hemolytic colonies resembling GBS. The suspected colonies were Gram-stained, and those with gram-positive cocci were examined for GBS. The Todd-Hewitt broth cultures were also plated out on CNA or SXT agar the following day, and the same procedure was carried out to verify the readings of the primary plates.

If β-hemolytic colonies were present, one representative colony was picked and examined for growth of only group B β-hemolytic streptococci. The streptococcal strains were identified by Gram-staining, catalase test, B-lysin test (commercial CAMP test by Remel, Lenexa, KS), PYR test (Remel, Lenexa, KS), and, finally, direct testing with the Strep B grouping latex reagent from the PathoDx Strep Grouping kit (Diagnostic Products, USA). A patient was considered to be vaginally colonized with GBS if GBS organisms were isolated from the vaginal specimens. Serotyping was not performed on the GBS isolates; the GBS positive colonies were isolated and frozen in a milk medium for future serotyping.

SPSS for Windows (Version 7) (Chicago, IL) was used for data management and statistical analysis. The sensitivity, specificity, and positive and nega-

TABLE 1. Sample characteristics

| Variable | Mean ± SD* (range) or % |
|---|---|
| Age | 48.5 ± 12.4 (28–80) |
| Gravidity | 2.6 ± 2.4 (0–15) |
| Parity | 1.9 ± 2.0 (0–15) |
| Race | |
| Caucasian | 52 |
| African-American | 43 |
| Hispanic | 4 |
| Other | 1 |

*SD = standard deviation.

tive predictive values of the Strep B OIA test, compared to the GBS selective CNA/SXT culture and broth-enhanced culture, were assessed.

## RESULTS

The sample characteristics are shown in Table 1 and the culture and OIA results in Table 2. A total of 29 samples were positive by culture methods, yielding a sample prevalence rate of 20.6% for vaginal GBS colonization. The sample sensitivity and specificity of the OIA method were 58.6% and 85.7%, respectively. These values are lower than the sensitivity and specificity values of 85.4% and 91.5%, respectively, that are given in the OIA package insert.[10] Although the sample negative predictive value was fairly high (88.9%), the positive predictive value was low (51.5%).

## DISCUSSION

Group B streptococci are the most common cause of neonatal sepsis and can result in serious morbidity and mortality for the infant patient. Attack rates are also related to the size of the maternal inoculum present in the genital tract. Neonates born to mothers who are heavily colonized with GBS are at greater risk for developing early-onset disease.[7] However, there have been studies that show significant morbidity and mortality from GBS disease in neonates born to lightly colonized patients as well.[7,13] Thus, an effective and reliable intrapartum screening method should have adequate sensitivity for identifying GBS even in specimens with a low inoculum size.

A simple and reliable rapid test capable of accurately identifying GBS would be an extremely important tool in the prevention of neonatal GBS disease.[11] Various rapid assays are commercially available today for the detection of GBS, but none are commonly used due to poor sensitivity.[12,13] Caroll

TABLE 2. Culture and strep OIA test results

| | Strep OIA test result | |
|---|---|---|
| Culture result | Negative (n = 108) | Positive (n = 33) |
| Negative (n = 112) | 96 | 16 |
| Positive (n = 29) | 12 | 17 |

et al. reported that of the multiple immunoassays that are available today, the Strep B OIA test had the highest sensitivity only in the face of heavy colonization (greater than $10^6$ colony forming units/ml).[14] Under light colonization, the sensitivity was poor. In our study, the Strep B OIA test appears to have the same drawback, with low sensitivity and low specificity. Although Baker et al. reported a sensitivity of 82.5% and a specificity of 91.8% for the OIA test, they used trypticase soy agar containing 5% sheep blood for their cultures.[15] Our study used a selective medium for Gram-positive organisms, CNA, and a specific medium for -hemolytic strep, SXT. By using selective media for GBS verified by broth-enhanced cultures (Todd-Hewitt), we believe that we obtained a more accurate culture gold standard for evaluating the performance of the Strep B OIA test. Thus, our results call into question the utility of the Strep B OIA test for diagnosing vaginal GBS.

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