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, gynec- 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.

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. The GBS infection rate is approximately one to three per 1000 live births and carries with it a mortality rate of 20%. 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.

Colonization with GBS is common among pregnant women, with an incidence of 15% to 40%. 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. 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. 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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prolonged rupture of membranes, a previously-
GBS-affected sibling, heavy maternal GBS coloni-
zation, 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 trans-
ported in a compact medium until they can be pro-
cessed and cultured. The standard culture method
is both sensitive and specific, but because this pro-
cedure 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 anti-
body 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 spe-
cific 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 coloni-
zation with GBS.

MATERIALS AND METHODS
A total of 141 patients participated in this study.
Vaginal cultures were obtained preoperatively from
nonpregnant gynecologic patients undergoing ma-
jor gynecological surgery, which comprised benign
gynecologic surgery, gynecologic oncology surgery,
and urogynecologic surgery. All of the patients pre-
sented 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 ap-
plicators. The swabs were rubbed against the vagi-
nal 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 Cul-
turette II brand transport medium (Remel, Len-
exa, KS), and were mixed equally between the
pledget and the swabs by external compression on
the transport tube. The specimens were then de-
ivered to the laboratory at ambient temperature for
analysis. The processing of the specimens was per-
formed 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 sulf-
methoxazole-trimethoprim (SXT) agar, and incu-
bated 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 cul-
tures 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 colo-
nies 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 repre-
sentative 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 (Re-
mel, 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 iso-
lated from the vaginal specimens. Serotyping was
not performed on the GBS isolates; the GBS posi-
tive 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-
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. 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. However, there have been studies that show significant morbidity and mortality from GBS disease in neonates born to lightly colonized patients as well. 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. Various rapid assays are commercially available today for the detection of GBS, but none are commonly used due to poor sensitivity. Caroll 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). 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. 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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