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Evaluation of a rapid, real-time intrapartum group B *Streptococcus* assay

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Abstract

OBJECTIVE—To evaluate an intrapartum nucleic acid amplification test (NAAT) for Group B streptococcus (GBS).

STUDY DESIGN—Prospective cohort study of 559 women comparing intrapartum GBS culture with antepartum culture and intrapartum NAAT.

RESULTS—GBS prevalence was 19.5% by antepartum culture and 23.8% by intrapartum culture. Compared with intrapartum culture, antepartum culture had 69.2% sensitivity (60.6–76.9) and 96.0% specificity (93.7–97.7). The NAAT demonstrated sensitivity of 90.8% (84.6–95.2), specificity of 97.6% (95.6–98.8), and predictive values exceeding 92%. The incidence of discordant cultures was 10.4%. Of the women with negative antepartum and positive intrapartum cultures, only 1 (2.4%) received intrapartum antibiotics. Compared with white women, black (P=0.02) and Hispanic (P=0.02) women were more likely to have discordant cultures.

CONCLUSION—This intrapartum NAAT has excellent characteristics. It may be superior to antepartum culture for detecting intrapartum GBS—allowing more accurate management of laboring mothers and reducing neonatal GBS sepsis.

Keywords

Group B Streptococcus; intrapartum assay; intrapartum screening; neonatal sepsis

INTRODUCTION

Although universal screening and intrapartum antibiotic prophylaxis have substantially decreased the incidence of Group B streptococcus (GBS) disease in neonates, GBS remains a leading cause of neonatal morbidity and mortality in the United States.[1,2] Administration

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of intrapartum antibiotics is based on maternal GBS colonization status as determined by culture-based screening performed at 35 to 37 weeks of gestation. The Centers for Disease Control and Prevention (CDC) recommends universal screening of pregnant women and specifies a culture procedure requiring incubation for up to 48 hours, which precludes intrapartum screening. The CDC guidelines indicate that a negative screening test becomes invalid after five weeks.[3]

GBS colonizes the gastrointestinal or genitourinary tracts in 15–35% of pregnant and nonpregnant women. Colonization can be chronic, transient, or intermittent.[4–6] Therefore, the timing of GBS screening is important, and it is recommended that obstetricians screen women in the late third trimester to improve the likelihood that the antepartum culture reflects the true intrapartum colonization status. However, studies demonstrate that antepartum culture has sensitivity as low as 50% and positive predictive value below 60%, as well as less than ideal specificity.[7–11]

Despite compliance with universal screening, the majority (52.5%–82.3%) of neonates developing GBS sepsis were born to women who screened negative in the late third trimester and thus did not receive antibiotic prophylaxis.[12–14] This suggests that either the culture is insufficiently sensitive or the woman's colonization status changes between screening and delivery.

Prior studies of rapid nucleic acid amplification tests (NAAT) for intrapartum detection of GBS suggest that intrapartum screening may more accurately reflect intrapartum GBS colonization.[7–9,15,16] Accurate intrapartum testing could allow for more appropriate clinical management of mothers and newborns, including properly targeted intrapartum antibiotic prophylaxis for laboring women and appropriate neonatal sepsis evaluations. Ultimately, a more accurate screening test may further decrease the incidence of GBS disease.

The purpose of our study was to evaluate the test characteristics of a rapid, real-time intrapartum GBS NAAT by evaluating it against an intrapartum culture and comparing it with the antepartum screening culture in a busy delivery unit. Unlike previous studies, we collected data on maternal race and ethnicity and assessed the incidence of neonatal sepsis evaluations and neonatal intensive care unit admissions (NICU).

MATERIALS AND METHODS

This was a prospective cohort study of pregnant women presenting to the Labor and Delivery unit at Beth Israel Deaconess Medical Center (Boston, MA) from January through June 2010. IRB approval was obtained, and all women provided informed consent. Women 18 years of age and older with documented antepartum GBS culture results were eligible if they had not yet received intrapartum intravenous antibiotics. Eligible women were approached for participation seven days of the week, during day and night shifts, depending on the availability of the physicians obtaining consent and collecting samples. Maternal race/ethnicity was self reported.

Sample collection

Two intrapartum recto-vaginal samples were collected simultaneously per CDC guidelines by one of three obstetrician-gynecologists. Following collection, the samples were brushed together to ensure uniform specimen on each swab. A charcoal swab was used for the intrapartum culture, and the swab used for the intrapartum NAAT (Xpert GBS Assay, Cepheid, Sunnyvale, CA) was included in the kit.

GBS culture

Results of the antepartum screening culture were obtained from each participant's medical record. Antepartum cultures were performed according to CDC guidelines at either our institution's CLIA-certified clinical laboratory or one of two outside CLIA-certified laboratories. Study personnel were blinded to which laboratory conducted the antepartum culture.

The intrapartum GBS culture was performed by our institution's laboratory, which was blinded to antepartum culture and intrapartum NAAT results. All cultures were performed at 35°C in 5% CO_2. Charcoal swabs were inoculated into Todd-Hewitt broth containing gentamicin (8 μg/mL) and nalidixic acid (15 μg/mL) supplemented with 5% defibrinated sheep blood, and incubated for 18–24 hours. Broths were subcultured to tryptic soy agar plates containing 5% defibrinated sheep blood, incubated for 18–24 hours, and examined for beta-hemolytic streptococci or possible non-hemolytic GBS. The presence of GBS was identified by latex agglutination with GBS-specific antiserum. If no GBS were present after 24 hours of incubation, the subculture was reincubated for 18–24 hours and reexamined for confirmation.

Intrapartum NAAT

The intrapartum NAATs were purchased from Cepheid and conducted according to the instructions. All tests were run by one investigator who was trained by an industry representative and blinded to antepartum and intrapartum culture results. The same investigator ran one positive and one negative control for each lot within each shipment of assay kits. A pure culture of GBS in a suspension at a density equivalent to 0.5 McFarland units diluted 1:100 was used for the positive control and the same density equivalent of enterococcus or alpha-hemolytic streptococcus was used for the negative control. Controls were provided by our institution's laboratory.

Each single-use kit includes reagents to detect GBS, a sample-processing control, and an internal control. The GBS primers and probe target a 3' DNA region adjacent to the *cfb* gene. If the intrapartum NAAT did not yield a positive or negative result secondary to a technical issue, the test was repeated with a new cartridge as per the package insert whenever an additional sample was available.

The intrapartum NAAT results were not used for clinical care; participants were treated based on the antepartum culture results per CDC guidelines. Results of the antepartum culture, the intrapartum culture, and the intrapartum NAAT were read independently of each other and recorded in separate locations.

Neonatal data

We extracted neonatal data from the medical records and assessed whether any of the following CDC-defined risk factors for neonatal GBS disease were present: intrapartum fever, chorioamnionitis, rupture of membranes for more than 18 hours, and positive maternal GBS antepartum culture. Adequate intrapartum antibiotic prophylaxis was defined as initiated at least four hours before delivery.

Statistical analysis

Based on previous studies and data from the manufacturer, we conservatively hypothesized a sensitivity of 85% for the antepartum culture and 91% for the NAAT.[9,11] A sample size of 490 women was needed to yield 80% power to detect that difference for a two-sided test with α=0.05.

All analyses were performed using SAS 9.2 (SAS institute Inc., Cary, NC). All tests were two sided, and P values <0.05 were considered statistically significant. Data are presented as mean and standard deviation (SD), median and interquartile range, or proportion and 95% confidence interval (CI). Comparisons were made using a Chi-square or Fisher's exact test for categorical variables and parametric or non-parametric tests for continuous variables, as appropriate. The intrapartum GBS culture was considered the gold standard. Sensitivity, specificity, predictive values, and 95% CIs were calculated. Samples with an indeterminate NAAT result were excluded from the denominator in calculations of sensitivity, specificity, and prevalence for the primary analysis. We also calculated the test characteristics assuming that the indeterminate NAAT results were not in agreement with the intrapartum culture.

CDC guidelines specify that a negative antepartum GBS culture is valid for five weeks. Thus, we performed a sensitivity analysis excluding women for whom more than five weeks elapsed between the antepartum and intrapartum cultures to recalculate test characteristics of the antepartum culture. We compared the incidence of discordant culture results among women with five weeks or less between the antepartum and intrapartum cultures to women with more than five weeks between cultures.

RESULTS

Among 559 women who delivered 563 neonates, the mean maternal age was 32.0 (±5.4) years and mean gestational age at enrollment was 39.4 (±1.25) weeks. Additional participant characteristics are shown in Table 1. The prevalence of GBS rectovaginal colonization was 19.5% (16.3–23.0) with antepartum culture, 23.8% (20.3–27.6) with intrapartum culture, and 23.6% (20.1–27.4) with the intrapartum NAAT. The mean interval between the antepartum and intrapartum tests was 3.5 (±1.4) weeks.

Among 133 women colonized with GBS by intrapartum culture, the antepartum screening culture was positive for 92 (69.2%) women, while the intrapartum NAAT was positive for 119 (90.8%). The results of all three tests are summarized in Table 2.

Both sensitivity and negative predictive value of the intrapartum NAAT were significantly superior to the antepartum culture. Although specificity and positive predictive value were higher with the NAAT than antepartum culture, the differences did not reach statistical significance. The test characteristics of the antepartum culture and intrapartum NAAT compared with intrapartum culture are displayed in Table 3.

The incidence of discordance between antepartum and intrapartum GBS cultures was 10.4%; 41 (7.3%) women converted from negative to positive and 17 (3.0%) from positive to negative. Participant characteristics and outcomes stratified by concordance of GBS cultures are shown in Table 4. The mean interval between the antepartum and intrapartum tests and the mean gestational age at testing was the same for women with concordant and discordant results.

The incidence of discordant GBS culture results was lowest among Asian women and highest for Hispanic and black women. Compared with white women, black (P=0.02) and Hispanic (P=0.02) women were significantly more likely to have discordant results.

Of the 450 women with a negative antepartum culture, 409 (90.9%) remained negative at the intrapartum culture and 41 (9.1%) converted to positive. Among the 41 who converted from negative to positive, the intrapartum NAAT was positive in 33. This yielded a sensitivity of 80.5% (65.1–91.2). Forty (97.6%) of these women did not receive intrapartum antibiotic prophylaxis.

Of the 109 women with a positive antepartum culture, 92 (84.4%) had a positive intrapartum culture and 17 (15.6%) converted to negative. Among the 17 who converted from positive to negative, the intrapartum NAAT was negative in 11. As shown in Table 4, 5 (29.4%) of these women had an infant who underwent a sepsis evaluation, as compared to 73 (17.9%) of the 409 women who remained negative (P=0.21). All of the 17 women who converted from positive to negative received intrapartum antibiotic prophylaxis; 11 (64.7%) received adequate prophylaxis.

More than five weeks elapsed between the antepartum and intrapartum cultures for 53 (9.5%) women. The incidence of discordant cultures among these women was 13.2%, which was not significantly different from the incidence of 10.1% among women for whom the time interval was five weeks or less (P=0.48). When excluding these 53 women, the sensitivity (70.6%), specificity (95.9%), positive predictive value (84.0%), and negative predictive value (91.4%) of the antepartum culture were essentially unchanged. Although not statistically significantly different, the sensitivity (57.1%: 28.9–82.3) and negative predictive value (86.4%: 72.7–94.8) of the antepartum culture were lower among the 53 women with more than five weeks between cultures.

With the first attempt, the intrapartum NAAT did not yield a result for 73 (13.1%) samples. The specific result was error, invalid or no result for 58 (10.4%), 14 (2.5%), and one (0.2%) sample, respectively. The assay was repeated for 72 samples and a result was obtained for all but 11 (9 errors, 1 invalid and 1 no result). Ultimately, 12 (2.1%) samples had indeterminate NAAT results. When assuming that these 12 indeterminate NAAT results were not in agreement with the intrapartum culture, the results were similar to the primary analysis in which indeterminate NAAT results were excluded: sensitivity of 89.5% (83.0–94.7), specificity of 95.3% (92.8–97.1), positive predictive values of 85.6% (78.7–91.0) and negative predictive value of 96.7% (94.5–98.2).

The time to prepare a sample for processing was less than five minutes. Processing time was 50 minutes or less for 99.6% of samples. When the sample was positive, the NAAT yielded a result in a median time of 41.0 (39.0–44.0) minutes; the median time was 48.0 (48.0–49.0) minutes for a negative result, 8.0 (7.0–8.0) minutes for error, and 48.0 (48.0–49.0) minutes for invalid. In the one instance when `no result' was obtained, that information was available immediately.

COMMENT

Our results demonstrate that the test characteristics of a real-time intrapartum NAAT are superior to those of the antepartum culture used to guide treatment in the intrapartum period. Using intrapartum GBS culture as the gold standard, the sensitivity and specificity of the intrapartum NAAT were 90.8% and 97.6%, respectively, while sensitivity of the antepartum culture was only 69.2% and its sensitivity 96.0%. Thus, screening with antepartum culture does not accurately reflect intrapartum colonization status in some women, leaving a group of neonates vulnerable to GBS disease and exposing a substantial proportion of mothers and fetuses to potentially unnecessary antibiotic prophylaxis.

Prior studies of the Xpert GBS Assay found similarly strong test characteristics with sensitivity from 85.0–98.5% and specificity of 96.0–99.6%.[8,15,16] In contrast, one study showed that the intrapartum NAAT was not very specific (64.5%) but had a sensitivity of 95.8%.[9] While our data showed a significantly higher sensitivity of the intrapartum NAAT compared with antepartum culture, other studies did not assess statistical significance or lacked adequate power.

Given the transient nature of GBS colonization, the ideal screening test would occur in the intrapartum period. In our study, the incidence of discordance was 10.4% between the antepartum and intrapartum cultures, which is similar to other reports.[9,10] Discordance was not related to the interval between cultures, as the interval was similar for women with concordant and discordant results.

The incidence of discordant GBS cultures suggests that an intrapartum NAAT would result in more appropriate management of mothers and infants at risk for perinatal GBS transmission. This is particularly important given that the majority of neonatal GBS sepsis occurs in infants born to mothers with a negative antepartum screening culture.[12–14] In our study, 9.1% of the women with a negative antepartum culture had a positive intrapartum culture; virtually all of these women (97.6%) received no intrapartum antibiotic prophylaxis. The intrapartum NAAT was positive in 80.5% of these women, suggesting that the intrapartum NAAT could improve the ability to appropriately provide intrapartum prophylaxis to these women, thereby potentially reducing the incidence of neonatal sepsis.

Among women with a positive antepartum culture, 15.6% later had a negative intrapartum culture. All of these women received intrapartum antibiotic prophylaxis, and 29.4% of their infants underwent sepsis evaluation. The specificity of the NAAT was 64.7% for these women; thus, use of the intrapartum NAAT could reduce unnecessary antibiotic use and neonatal sepsis evaluation.

Overall, our results show high concordance between the intrapartum NAAT and intrapartum culture. However, among women with discordant cultures, the intrapartum NAAT demonstrated lower sensitivity and specificity. There is speculation that the NAAT may result in minute concentrations of GBS being amplified that cannot be detected by culture; however, the lower sensitivity and specificity among both negative to positive and positive to negative results make this theory less likely. This finding is reassuring in that it suggests that NAAT is unlikely to identify a clinically irrelevant amount of GBS.

We obtained an intrapartum NAAT result for 86.9% of samples after one attempt and in all but 2.1% after two attempts. These findings are consistent with two other studies,[2,16] but somewhat higher than in one report.[15] When the NAAT did not yield a determination of colonization, the most common result was error, which was returned in a median time of 8.0 minutes. Furthermore, a substantial proportion of these errors may be eliminated with newer kits, which eliminate manual loading of the reagents.

The 48 hours needed for GBS cultures generally prohibits their use for intrapartum screening. Our study demonstrates that intrapartum NAAT results can be obtained within 60 minutes; suggesting that it could allow for adequate maternal antibiotic prophylaxis in many deliveries, given the median time from admission to delivery of 7.8 hours for term births reported by Van Dyke et al.[14] Prior studies have demonstrated the feasibility of intrapartum NAAT screening for GBS.[8,16] Furthermore, even when mothers deliver shortly after admission without appropriate prophylaxis, the test result could guide neonatal management.

The CDC indicates that intrapartum NAAT screening may be useful in certain situations, such as unknown GBS colonization status at term.[3] Intrapartum screening may also be useful in preterm deliveries, given the high burden of GBS disease in this population. Our study reveals several other populations that may receive particular benefit from intrapartum NAAT. First, our data suggest potentially meaningful differences in the incidence of antepartum and intrapartum culture discordance in Hispanic and black women. These findings have not been reported previously and warrant further investigation to confirm whether some populations are at higher risk of discordant GBS cultures. Notably, GBS prevalence has been shown to be higher in these racial/ethnic groups.[1] Additionally, 9.5% of

women in our study presented to labor and delivery more than five weeks after their antepartum culture result was obtained, an interval that is known to reduce the utility of the antepartum test.[3] This population also may benefit from intrapartum NAAT.

Despite widespread adoption of universal screening, two-thirds of neonates who develop GBS sepsis are born to women with a negative antepartum screening culture. This, coupled with the incidence of discordant GBS culture results between the antepartum and intrapartum periods, suggests a need for intrapartum GBS testing. The latest CDC guidelines suggest that in order to be clinically useful, an intrapartum GBS screening test must be performed at the bedside by labor and delivery staff, have a turn-around time of less than 30 minutes, and have a sensitivity and specificity greater than 90%. In our study, results were obtained within 60 minutes and the sensitivity and specificity exceeded 90%. Our results suggest that the rapid NAAT has the potential to be a clinically meaningful intrapartum test and may lead to more accurate identification of intrapartum GBS colonization, thereby allowing for more appropriate management of mothers and neonates and reducing the incidence of neonatal GBS sepsis.

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Table 1

Participant characteristics

	All women n=559
Maternal age (yrs)	32.0 ± 5.4
Race/Ethnicity	
White	338 (60.5)
Asian/Pacific Islander	77 (13.8)
Black	74 (13.2)
Hispanic	53 (9.5)
Other or >1 race/ethnicity	17 (3.0)
Gestational age at enrollment (wks)	39.4 ± 1.25
Method of delivery	
Vaginal	407 (72.8)
Cesarean	152 (27.2)
Number of gestations	
Singleton	555 (99.3)
Multiple	4 (0.7)

Data are presented as mean ±standard deviation or n (%)

Table 2

Antepartum culture and intrapartum NAAT results compared with intrapartum culture results

	Intrapartum culture result		
	Positive	**Negative**	**Total**
Antepartum culture result			
Positive	92	17	109
Negative	41	409	450
Total	133	426	559
NAAT result			
Positive	119	10	129
Negative	12	406	418
Indeterminate	2	10	12
Total	133	426	559

Table 3

Antepartum culture and intrapartum NAAT characteristics

Characteristic	Antepartum Culture % (95% CI)	NAAT % (95% CI)
Number of samples tested	559	547*
Sensitivity	69.2 (60.6–76.9)	90.8 (84.6–95.2)
Specificity	96.0 (93.7–97.7)	97.6 (95.6–98.8)
Positive predictive value	84.4 (76.2–90.6)	92.3 (86.2–96.2)
Negative predictive value	90.9 (87.8–93.4)	97.1 (95.0–98.5)

*12 rapid tests did not yield results

Table 4

Participant characteristics and outcomes stratified by concordance of GBS cultures

	Concordant n=501	Discordant n=58	P	Remained Negative n=409	Positive to Negative n=17	P	Remained Positive n=92	Negative to Positive n=41	P
Maternal age (yrs)	32.1 ± 5.1	30.5 ± 7.1	0.09	32.3 ± 5.1	31.0 ± 6.3	0.31	31.4 ± 5.4	30.3 ± 7.5	0.39
Gestational age (wks)									
Antepartum culture	35.9 ± 0.9	35.7 ± 0.7	0.15	35.8 ± 0.9	35.7 ± 0.7	0.66	36.0 ± 0.9	35.7 ± 0.7	0.04
Intrapartum culture	39.4 ± 1.3	39.2 ± 1.3	0.31	39.4 ± 1.3	39.0 ± 1.6	0.23	39.4 ± 1.1	39.3 ± 1.3	0.51
Interval between cultures (wks)	3.5 ± 1.3	3.5 ± 1.5	0.99	3.5 ± 1.3	3.2 ± 1.4	0.40	3.4 ± 1.4	3.6 ± 1.5	0.46
Race/ethnicity			0.008			0.09			0.16
White	309 (61.7)	29 (50.0)		254 (62.1)	11 (64.7)		55 (59.8)	18 (43.9)	
Asian/Pacific Islander	74 (14.8)	3 (5.2)		66 (16.1)	0 (0.0)		8 (8.7)	3 (7.3)	
Black	61 (12.2)	13 (22.4)		43 (10.5)	5 (29.4)		18 (19.6)	8 (19.5)	
Hispanic	43 (8.6)	10 (17.2)		34 (8.3)	1 (5.9)		9 (9.8)	9 (22.0)	
Other or >1 race/ethnicity	14 (2.8)	3 (5.2)		12 (2.9)	0 (0.0)		2 (2.2)	3 (7.3)	
NAAT result			<0.0001			<0.0001			0.01
Positive	91 (18.2)	38 (65.5)		5 (1.2)	5 (29.4)		86 (93.5)	33 (80.5)	
Negative	399 (79.6)	19 (32.8)		395 (96.6)	11 (64.7)		4 (4.4)	8 (19.5)	
Indeterminate	11 (2.2)	1 (1.7)		9 (2.2)	1 (5.9)		2 (2.2)	0	
Neonatal sepsis evaluation	98 (19.6)	14 (24.1)	0.41	73 (17.9)	5 (29.4)	0.21	25 (27.2)	9 (22.0)	0.52
Any NICU admission	112 (22.4)	14 (24.1)	0.76	83 (20.3)	5 (29.4)	0.36	29 (31.5)	9 (22.0)	0.26

Data are presented as mean ± standard deviation or n (%)