HHS Public Access

Author manuscript

J Perinatol. Author manuscript; available in PMC 2019 September 01.

Published in final edited form as:

J Perinatol. 2019 March ; 39(3): 433–438. doi:10.1038/s41372-018-0308-3.

Racial disparities in intrapartum group B streptococcus colonization: a higher incidence of conversion for African American women

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Abstract

Objective: To compare the incidence of Group B *Streptococcus* (GBS) conversion from a negative antepartum to a positive intrapartum culture among women who self-identify as non-Hispanic black, Hispanic, or non-Hispanic white.

Study Design: This was a prospective cohort study of women with a negative rectovaginal GBS culture within 35 days of enrollment. An intrapartum rectovaginal swab was collected and cultured for GBS. Data were compared with chi-square, Fisher's exact, or Wilcoxon rank-sum test. Modified Poisson regression was used.

Results: We enrolled 737 women; 75.4% were non-Hispanic white, 17.6% were non-Hispanic black, and 6.9% were Hispanic. Non-Hispanic black women were more likely to convert to GBS positive than non-Hispanic white women, 9.2% as compared to 5.3% (RR: 2.0; 95% CI: 1.02–3.8).

Conclusion: The increased incidence of positive intrapartum GBS cultures among non-Hispanic black women suggests that non-Hispanic black race is a risk factor for GBS conversion in the late third trimester.

Introduction

Group B Streptococcus (GBS) remains a leading cause of early-onset neonatal sepsis in the United States. Even with universal screening, the incidence of early-onset invasive GBS disease among term black infants is triple that of white infants.[1] Adequacy of prenatal care, prematurity, and socioeconomic status have not explained these differences.[2] The Centers for Disease Control and Prevention (CDC) urges "continued monitoring of early-onset GBS disease among black infants to determine whether additional interventions are warranted."[3] Variation in the prevalence and pattern of GBS colonization between white and black

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Disclosure of Interests: The authors report no conflict of interest.

women may explain this disparity. Given colonization can be transient, a woman who screened negative in the late third trimester may convert to positive by delivery. This may explain why the majority of infants with GBS sepsis are born to women who screened negative and thus do not receive antibiotic prophylaxis.[4–6] Previous studies have reported that antepartum GBS culture sensitivity ranges from 51–87% when compared with intrapartum culture, which likely reflects conversion, though may reflect inadequate sampling or laboratory error.[7–10] Studies have shown a 7–10% incidence of negative to positive conversion between the recommended screening and intrapartum period.[10–13]

Previously, we demonstrated that among women with a negative antepartum GBS culture, the incidence of conversion was higher in non-Hispanic black (15.7%) and Hispanic women (20.9%) than non-Hispanic white women (6.6%).[10] The aforementioned study was not powered to evaluate racial differences in conversion. Another study performed in the Netherlands attempted to explore racial and socioeconomic differences in GBS colonization, however this study did not evaluate these factors in relation to GBS conversion.[11] Thus, we aimed to further investigate GBS conversion among non-Hispanic black, Hispanic and non-Hispanic white women as a possible explanation for the racial disparity in early-onset GBS disease.

Materials and Methods

This was a prospective cohort study of pregnant women with a negative antepartum GBS culture who presented for delivery at our institution from March 2015 through December 2016. Funding was provided by the William F. Milton Fund, a Harvard University endowment fund, which awarded the grant based on an external peer review for scientific quality. The Committee on Clinical Investigations at Beth Israel Deaconess Medical Center approved this research (Protocol #2015P-000016), and all women provided informed consent. Women aged ≥18 years with a documented negative GBS culture within 35 days of admission for delivery were approached for consent if they had not received intrapartum antibiotics. Our primary outcome was the incidence of GBS conversion from a negative antepartum culture to a positive intrapartum culture. Secondary outcomes included-intrapartum fever, mode of delivery, and neonatal intensive care (NICU) admission for sepsis evaluations.

Maternal race, height, and weight were self-reported by participants at enrollment. We confirmed maternal height and weight from the medical record. We extracted other maternal and neonatal data from the medical record, including preterm rupture of membranes and presence of labor, prolonged rupture of membranes (>18 hours), intrapartum fever, positive GBS culture in a prior pregnancy, and presumed neonatal sepsis as defined by the neonatologist with either a positive blood culture or treatment with intravenous antibiotics for longer than 72 hours. The investigators who conducted the medical record review were blinded to the intrapartum culture results.

Sample collection and GBS culture

Antepartum rectovaginal cultures were collected in the primary obstetrician's office by a clinician, in accordance with guidelines of the CDC, and processed at a community- or

hospital-based laboratory that was Clinical Laboratory Improvement Amendments (CLIA)-certified.[9] We confirmed the results and the timing of the antepartum screening culture in each participant's medical record before enrollment.

Obstetrical providers collected intrapartum cultures per CDC-recommended method of sample collection by swabbing the vaginal introitus followed by the rectum, ensuring to insert the swab though the anal sphincter. The swabs were processed by the CLIA-certified clinical laboratory at our institution per routine protocol. The laboratory was blinded to each participant's antepartum culture result. The result of the intrapartum culture was not used for clinical care and was not part of the medical record.

All culture swabs were inoculated in Strep B Carrot Broth™ (Hardy Diagnostics, CA) which utilizes Granada Medium reaction and contains the necessary components for pigment detection of beta-hemolytic GBS colonies. All cultures were incubated in a 35°C in non-carbon dioxide incubator for 6–24 hours. If after this incubation, red or orange color was noted, then GBS culture was reported as positive. If no orange or red color was present, a subculture was performed and applied to GBS Detect™ (Hardy Diagnostics, CA) agar plate to assist in the isolation and identification of the non-hemolytic and alpha-hemolytic strains of GBS. These plates were incubated overnight under the same conditions in the non-carbon dioxide incubator. If there was no growth or no beta-hemolytic colonies, results were reported as negative for GBS. A subculture to a TSA plates with 5% Sheep Blood (BAP) and incubation overnight in the same non-CO_2 incubator was performed if one of the following two circumstances occurred (1) mostly non-hemolytic bacteria were detected, but also a small number of tiny colonies with a good size beta-hemolysis or (2) there were beta-hemolytic colonies and insufficient growth. If GBS was identified in this subculture, then results were deemed positive for GBS colonization.

Statistical Analysis

We performed a power calculation using the incidence of negative to positive GBS culture conversion for non-Hispanic white (6.6%), Hispanic (20.9%) and non-Hispanic black women (15.7%) from our prior study.[10] Based on our patient population, we assumed a 1:5 ratio of non-Hispanic black to non-Hispanic white women and a 1:10 ratio of Hispanic to non-Hispanic white women. We also assumed that 10% of enrolled women would not have a sample collected or that the culture result would be unusable due to laboratory error. To achieve 85% power to detect the specific differences with these assumptions and a two-sided alpha of 0.05, we aimed to enroll 645 non-Hispanic white women, 129 non-Hispanic black women, and 49 Hispanic women.

Data were stored using Research Electronic Data Capture and analyzed using SAS 9.4 (SAS institute, Cary, NC; code available from the corresponding author).[15] We compared categorical data using a chi-square or Fisher's exact test and compared continuous data using the Wilcoxon rank-sum test. Modified Poisson regression was used to calculate risk ratios (RR) and 95% confidence intervals (CI).[15] We considered time between cultures as a potential confounder.

Results

We enrolled 780 women who identified as non-Hispanic white, non-Hispanic black or Hispanic. We excluded 10 (1.3%) women whose antepartum culture was more than 35 days before enrollment and 33 (4.2%) women who did not have a swab collected due to withdrawal from the study or delivery prior to collection. Of the 737 women included in the analysis, 556 (75.4%) were non-Hispanic white, 130 (17.6%) were non-Hispanic black, and 51 (6.9%) were Hispanic. We enrolled fewer non-Hispanic white women than originally intended due to a lower incidence of conversion than hypothesized, which resulted in an inability for us to reach our target power even if we had enrolled the full sample size. The three groups were similar with respect to age, body mass index and gestational age at enrollment (Table I). The vast majority of the patients that deliver at our institution receive prenatal care at offices within a 25-mile radius of our hospital. CDC risk factors for neonatal GBS disease, such as preterm delivery and intrapartum fever, were less common in non-Hispanic white women; however, non-Hispanic white women were more likely to experience prolonged rupture of membranes at term (Table I).

In our study population, which consisted only of women who had a negative antepartum GBS culture, 5.3% of women were positive for GBS colonization at the time of delivery. The incidence of negative to positive conversion was 4.7% among non-Hispanic white women, 9.2% among non-Hispanic black women, and 2.0% among Hispanic women (Table II). Non-Hispanic black women were significantly more likely to convert to GBS positive than non-Hispanic white women (RR: 2.0; 95% CI: 1.02–3.8). Non-Hispanic black women also were more likely to convert to GBS positive than Hispanic women (RR: 4.7; 95% CI: 0.68–35.3), though this difference was not statistically significant. Similarly, the lower incidence of conversion among Hispanic women compared with non-Hispanic white women was not statistically significant (RR: 0.42; 95% CI: 0.06–3.0). The median time between cultures was significantly shorter for non-Hispanic black and Hispanic women than non-Hispanic white women, (Table II), but adjusting for this potential confounder did not appreciably alter our risk ratios.

To assess whether converters and non-converters differed, we evaluated these groups within strata of race (Table III). We have provided this data only for non-Hispanic black and non-Hispanic white participants, because there was only one converter among Hispanic women, which does not allow for meaningful comparison. As shown in Table III, within both strata of race, converters and non-converters were similar with regard to all characteristics evaluated, except that among non-Hispanic black women, the gestational age at delivery was slightly lower for non-converters than converters.

Discussion

Main Findings

Our prospective study evaluated racial differences in the incidence of conversion from a negative antepartum GBS culture to a positive intrapartum culture. Our results demonstrate that despite a correctly-timed negative GBS culture in the late third trimester, 9.2% of cultures obtained from non-Hispanic black women were positive during the intrapartum

period. This incidence of conversion was higher compared to non-Hispanic white women. All participants had a negative antepartum culture within the 35-day CDC guideline, with a median time between cultures of roughly three weeks for all three groups. Non-Hispanic black and Hispanic women had a significantly shorter time between cultures, but the absolute difference was only about three days and not clinically significant. Further, when we evaluated the differences among converters and non-converters, gestational age at delivery was different but only by a few days, which is also not clinically significant. We observed a higher incidence of NICU admission for sepsis evaluation among Hispanic infants and a higher incidence of presumed neonatal sepsis among non-Hispanic black infants. Though these differences were not statistically significant, they may warrant future investigation.

Strengths and Limitations

Our study had several strengths. The study was performed prospectively; thus, we obtained maternal and neonatal data for all enrolled participants with a negative GBS culture consistent with CDC guidelines. All intrapartum cultures were processed by a single CLIA-certified laboratory, which was blinded to the antepartum culture. Finally, the study focused on the clinically-important negative to positive culture conversion since these pregnancies are at risk of inadequate intrapartum prophylaxis.

One limitation of our study was that it was not powered to detect differences in neonatal GBS sepsis. Based on national Active Bacterial Core surveillance data, to detect one case of GBS sepsis per group, we would have needed 2000 non-Hispanic black women and 7000 non-Hispanic white women.[1] In addition, both the incidence of conversion and the difference between groups were lower than we anticipated based on our prior study. Thus, an interim analysis demonstrated that we would not have achieved the desired power even if we had reached our target enrollment. This lower incidence of conversion may be due to improved antepartum GBS culture isolation by a more sensitive protocol, improved antepartum culture acquisition, or by chance. While we cannot exclude the possibility that specimen sampling may have more consistent intrapartum, it is unlikely that variability in sample collection would have differed by race and thus unlikely that sample collection would explain the observed differences. In the time between our two studies, our institution adopted a new laboratory protocol for GBS isolation which was thought to be both more cost effective and more sensitive. If the antepartum GBS screen is more sensitive in our current study, due to improved laboratory processing techniques, this could explain the lower observed false negative rate.

Interpretation

Our findings are consistent with other studies, including our prior study, which have documented that the discordance between late third-trimester and intrapartum GBS cultures or nucleic acid amplification (NAAT) testing is 0–21%.[10–13, 17–23] However, our study is unique in that it evaluated whether the discordance differs with respect to race, thereby attempting to evaluate antepartum screening prediction in these specific populations. Our findings also support results of our prior study suggesting racial disparities in the incidence of negative to positive GBS conversion between the antepartum and intrapartum periods.[10]

These studies support the notion that antepartum culture may be a suboptimal proxy for GBS colonization at delivery, particularly for women of non-Hispanic black race.

These results are clinically important as they highlight a racial disparity in GBS intrapartum colonization despite a correctly timed negative antenatal GBS culture. If non-Hispanic black women with a negative antenatal screen are more likely to enter labor with GBS colonization, they are less likely to receive intrapartum antibiotic prophylaxis and their infants are more likely to be exposed to GBS intrapartum. While our study did not find a correlation between discordant intrapartum colonization and the incidence of newborn GBS sepsis, these results raise the possibility that the discordant GBS screening contributes to the racial disparity in neonatal sepsis. As non-Hispanic black women are more likely to have a discordant intrapartum GBS screen and non-Hispanic black infants are more likely to develop early-onset GBS sepsis, there is an ongoing need for future investigation aimed at reducing the risk for this population. A repeat GBS culture closer to the delivery date or an intrapartum rapid nucleic acid amplification test may be necessary to address the incidence of false negative antepartum GBS culture in non-Hispanic black women. Prior studies of rapid nucleic acid amplification tests suggest that intrapartum screening may more accurately reflect intrapartum GBS colonization than the current recommended late preterm culture. [17, 19–22] Further studies are needed to evaluate better screening strategies in women more likely to convert their GBS culture status.

While our data demonstrate a higher incidence of conversion among non-Hispanic black women, our study did not investigate the etiology of this disparity. Due to consistent screening strategies and processing in a CLIA-certified lab, we believe that the disparate culture results most likely are due to an actual change in GBS carrier status. Although we cannot exclude the possibility of inadequate antepartum sampling or laboratory error, as reported in prior analyses,[7] these errors are unlikely to be disproportionate by race. Future investigations should evaluate the role of these factors in GBS conversion, as well as differences in the vaginal microbiome that may contribute to more frequent transient colonization.[24–25]

Our data demonstrate a higher incidence of GBS conversion between an appropriately-timed antepartum GBS culture and intrapartum culture in non-Hispanic black women compared to non-Hispanic white women. This disparity may partially explain the racial disparity in the incidence of early-onset neonatal GBS sepsis. Importantly, our findings are useful for future investigation to reduce the incidence of this disease, particularly in non-Hispanic black infants.

Acknowledgments

Funding: This study was funded by the William F. Milton Fund, a Harvard University Endowment Fund, and was conducted with support from Harvard Catalyst | The Harvard Clinical and Translational Science Center (National Center for Research Resources and the National Center for Advancing Translational Sciences, National Institutes of Health Award UL1 TR001102 and financial contributions from Harvard University and its affiliated academic healthcare centers.

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Table I.

Baseline characteristics at delivery and risk factors for GBS disease among women with a negative antepartum GBS culture

Characteristics	Non-Hispanic white n=556	Non-Hispanic black n=130	Hispanic n=51
Age (years)	33.3 ± 4.7	31.3 ± 5.9	31.6 ± 6.2
Body mass index (kg/m^2)	30.1 ± 5.5	32.5 ± 6.6	32.9 ± 5.1
Gestational age at enrollment (weeks)	38.9 ± 2.7	38.7 ± 1.7	38.7 ± 2.2
CDC Risk factors for neonatal GBS disease			
Delivery <37 weeks	33 (5.9)	13 (10.0)	7 (13.7)
Fever during labor	87 (15.7)	23 (17.7)	11 (21.6)
PROM (≥18hours) at term	40 (7.2)	1 (2.0)	4 (3.1)

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

CDC, Centers for Disease Control and Prevention; GBS, group B streptococcus; PROM, premature rupture of membranes

Table II.

Obstetric and neonatal outcomes of participants with a negative antepartum GBS culture

	Non-Hispanic white n=556	Non-Hispanic black n=130	P*	Hispanic n=51	P*
Maternal Outcomes					
GBS conversion (negative to positive)	26 (4.7)	12 (9.2)	0.04	1 (2.0)	0.72
Time between cultures (weeks)	3.3 ± 1.2	2.9 ± 1.3	0.002	2.9 ± 1.2	0.02
Time to conversion (weeks)	3.2 ± 1.1	3.2 ± 1.6	0.87	5.0 **	0.12
Intrapartum antibiotics before delivery †	18 (3.2)	4 (3.1)	1.0	3 (5.9)	0.41
Mode of delivery			0.06		0.91
Vaginal	429 (77.2)	90 (69.2)		39 (76.5)	
Cesarean	127 (22.8)	40 (30.8)		12 (23.5)	
Neonatal Outcomes					
NICU admission for sepsis evaluation	77 (13.9)	21 (16.2)	0.50	12 (23.5)	0.06
Presumed sepsis	3 (0.5)	2 (1.5)	0.24	0 (0.0)	0.24

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

*For the comparison with non-Hispanic white women

**Only one Hispanic woman converted from negative to positive; thus, a standard deviation could not be calculated

†Antibiotics for cesarean delivery or chorioamnionitis

GBS, group B streptococcus; NICU, neonatal intensive care unit

Table III.

Baseline characteristics at delivery and risk factors for GBS disease among women with a negative antepartum GBS culture

Characteristics	Non-Hispanic white n=556			Non-Hispanic black n=130		
	Conversion n=26	No conversion n=530	p	Conversion n=12	No conversion n=118	p
Age (years)	33.7 4±.5	33.3 ±4.7	0.71	30.8 ±6.0	31.4 ±5.9	0.73
Body mass index (kg/m^2)	29.1 ±7.5	30.2 ±5.3	0.48	32.6 ±8.5	32.5 ±6.4	0.97
Gestational age at enrollment (weeks)	39.1 ±1.0	38.9 ±2.8	0.39	39.5 ±1.0	38.6 ±1.7	0.02
CDC risk factors for neonatal GBS disease						
Delivery <37 weeks	0 (0.0)	33 (6.2)	0.39	0 (0.0)	13 (11.0)	0.61
Fever during labor	3 (11.5)	84 (15.9)	0.78	2 (16.7)	21 (17.8)	1.0
PROM (≥18hours) at term	0 (0.0)	40 (7.6)	0.25	0 (0.0)	4 (3.4)	1.0

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

CDC, Centers for Disease Control and Prevention; GBS, group B streptococcus; PROM, premature rupture of membranes