Determination of colonization of pregnant women at 35 to 37 weeks of gestation and at the time of delivery.

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Abstract:

Objectives: Approximately 10 to 30% of pregnant women carry group B streptococci in the vagina or rectum, and 2 to 3 children per 1000 live births develop GBS disease. The case fatality ratio for the disease is 4 to 6%. The CDC recommends that all pregnant women should be screened for GBS colonization at 35 to 37 weeks of gestation and GBS-positive women should receive prophylactic antibiotics at the time of delivery. We compared the GBS carriage rates in women at 35 weeks of gestation and during labour using Real-time PCR (IDI –Strep B) and also compared the performance of RT-PCR to a culture method.

Methods: Antepartum and intrapartum vaginal and rectal swabs (Copan) were collected. Antepartum swabs were vortexed in sample preparation buffer, $500~\mu L$ was used to inoculate selective Todd Hewitt broth and $50~\mu L$ was added to the IDI-lysate buffer. After overnight incubation, TH was subcultured to a Columbia blood agar plate. After further overnight incubation, the growth was screened for the presence of GBS. Amplification and detection of GBS product by IDI-Strep-B was performed according to the manufacturer's.

Results: By culture 69 of 249 pregnant women were positive at antepartum screening. IDI-Strep was positive in 67 of these cases and in an additional 3 patients. The antepartum carriage rate for GBS was 29.8% (72/249). Intrapartum specimens were available from 173 of 249 women. Of these, 46 were positive by antepartum culture and/or PCR. Forty of 46 remained culture and/or PCR positive. Significantly, 8 of 127 (6.2%) who tested negative at antepartum screening became positive for GBS at intrapartum screening. In total, 14/173 (8.09%) of women changed their GBS colonization status.

Conclusions: Our results show that a small but a significant number of women spontaneously changed their GBS colonization status by the time of delivery. In the population studied, of 123 women who were negative for GBS at the time of antepartum screening 8 became positive for GBS. Intrapartum screening, if feasible may more accurately detect GBS carriage in pregnant women.

Introduction:

Approximately 10 to 30% of pregnant women are colonized vaginally with group B streptococcus (GBS). Primarily, GBS are harbored in the rectum from where the organism may enter the vagina. A small number of newborns that become infected with GBS during vaginal delivery, or prior to delivery develop septicemia, meningitis, or other systemic infection, often with long-term adverse effects, despite prompt diagnosis and treatment. It has been shown that prophylactic antibiotics given during labour can prevent transmission of GBS from mothers to their newborns and therefore Group B streptococcal disease in newborns.

The CDC has recently updated its guidelines for reducing group B streptococcal disease in neonates and recommends universal screening at 35 to 37 weeks gestation for all pregnant women.

The IDI-Strep B test is the only FDA-approved rapid test for the detection of GBS colonization in pregnant women. In a clinical study of 802 pregnant women at five centres in the USA and Canada, the IDI-Strep B test identified 94% of GBS colonized women.

Primary Objectives:

- To establish the predictive value of prenatal screening for GBS colonization done at 35 to 37 weeks gestation by comparing with the results of vaginal/rectal swabs collected during labour.
- To compare the sensitivity and specificity of IDI-Strep B for the detection of GBS with those obtained with selective Todd-Hewitt enrichment broth (Oxoid) from the same clinical specimens.

Materials and Methods:

Women were recruited and were asked to sign a consent form during their antepartum visit at 35-37 weeks of gestation. Two vaginal/rectal swabs (Starplex Amies transpot media and Copan Venturi Transystem). Swabs were placed in the appropriate transport media and sent to the Microbiology Laboratory. Swabs submitted in Amies transport media was placed into 5 ml of Todd-Hewitt media with gentamicin ($5\mu g/ml$) and nalidixic acid ($15\mu g/ml$). After 18 to 24 hours of incubation at 35°C under 5% CO₂, the swab was used to inoculate a sheep agar plate. After overnight incubation, the plate was examined for growth and GBS were identified using standard methods. Copan swabs submitted on a liquid soaked sponge were placed in IDI-Strep B preparation buffer. The buffer was used to perform realtime PCR using the IDStrep B kit and Smartcycler. In addition, 500 μ l of preparation buffer was transferred into 5 ml selective Todd-Hewitt broth. The Todd-Hewitt broth was processed as described above.

During labour two vaginal rectal swabs were collected. Copan swabs were processed as above. Starplex swabs were used to perform realtime PCR per the IDI-Strep B test method.

Women received prophylaxis for GBS based on their antepartum results.

Results:

A total of 249 women were recruited and from all of them antepartum vaginal/rectal swabs were collected and processed. Of these 249, 69 women were positive by culture for GBS. GBS were isolated from direct swabs in 76 cases and from IDI-Strep B preparation buffer in all 69 cases.

	# of GBS-positive specimens by RT-PCR	# of GBS-negative specimens by RT-PCR
# of GBS-positive specimens by culture	67	2*
# of GBS-negative specimens by culture	5	177

^{*} Specimens positive for GBS from IDI-Strep B preparation buffer

Intrapartum specimens were available only from 173/249 women. Of these 46 were positive either by PCR or culture at the time of antepartum screening.

	# of GBS-positive women	# of GBS-negative women
	at intrapartum	at intrapartum
# of GBS-positive women	40	6
at antepartum		
# of GBS-negative women	8	119
at antepartum		

In total, 14/173 (8.09%) of women changed their GBS colonization status but more significantly 8/127 (6.2%) of women who were GBS negative at the time of antepartum screening became GBS positive prior to delivery.

Conclusions:

The IDI-Strep B test was more sensitive than a direct culture method and correctly identified 97.2% of women colonized with GBS at the time of antepartum screening. Our study also showed that a number of women may change their colonization status between antepartum screening and the onset of labor. Women who acquire GBS after antepartum screening would not receive antibiotic prophylaxis and could transmit GBS to their neonates. The IDI-Strep B test requires only 2 hours to perform and could be used to detect GBS colonization during labor.