

RAPID INTRAPARTUM TEST (STREP B OIA®) AND PRENATAL CULTURES FOR IDENTIFICATION OF GROUP B STREPTOCOCCAL (GBS) CARRIERS AT DELIVERY : A PROSPECTIVE STUDY

P. Melin, M. Schmitz, C. Tsobo, M.P. Hayette, P. De Mol
 Belgian Reference Laboratory for GBS, University Hospital of Liège, Liège, Belgium



Medical Microbiology
 CHU, B-23, Sart Tilman
 B 4000 Liège, BELGIUM
 Phone: (32)4 366 24 38; Fax: (32)4 366 24 40
 Email: Pierrette.Melin@chu.ulg.ac.be

ABSTRACT

Background: The efficacy of the prenatal screening-based approach recommended by the CDC to prevent neonatal GBS diseases could be improved by using a good rapid test performed at the onset of labor. To assess the Strep B OIA® test (BioStar, Boulder, Co), an optical immunoassay completed in 30 minutes, we initiated a 6-center study to compare it with prenatal screening cultures to identify GBS carriers at delivery or opportunities to initiate intrapartum antibioprophyllaxis (IAP).

Methods: For a total of 531 pregnant women included in the study, pairs of vaginal/anal specimens collected at 35-37 weeks and intrapartum vaginal specimens were plated onto colistin-nalidixic agar and then inoculated into selective LIM broth for the detection of GBS. Furthermore, on each intrapartum vaginal swab a Strep B OIA test was performed.

Results: GBS were recovered in culture from 87 prenatal screenings (16.4%) and from 71 specimens collected at delivery (14%). Strep B OIA test identified 47 positive specimens (9%). Respectively, for the identification of GBS carriers at delivery, sensitivity, specificity, positive and negative predictive values for prenatal screening cultures were 69%, 91%, 56% and 95% and for Strep B OIA tests they were 62%, 99%, 94% and 94%. Evaluating opportunities to start an IAP, based on Strep OIA test versus prenatal screening cultures, 44 IAP vs. 49 would have been useful, 3 vs. 38 useless ($P < 0.001$) and 24 vs. 22 missed.

Conclusion: To identify GBS carriers, intrapartum screening Strep B OIA test, is equally sensitive to prenatal screening cultures and would allow a highly significant reduction of useless IAP.

BACKGROUND

In Europe as in North America, Group B streptococcus (GBS) is a leading cause of sepsis, meningitis and death among neonates. The efficiency of the prenatal screening based approach recommended by the CDC (1996)* to prevent neonatal GBS disease has been demonstrated. But an accurate rapid screening test for GBS performed at the onset of labor could improve this strategy: it would obviate the need for prenatal screening and would reduce the use of antibiotic for intrapartum chemoprophylaxis (IAP) in women who are not vaginal carriers at the time of delivery. Any identified GBS carriers at delivery means an opportunity to initiate IAP.

OBJECTIVES

To assess the Strep B OIA® test (BioStar, Boulder, Co, USA), an optical immunoassay completed in 30 minutes, in identifying GBS colonization in pregnant women at the time of delivery by comparison to recommended prenatal screening cultures.

STUDY DESIGN & METHODS

Population and setting

531 pregnant women hospitalized in 1999 in 6 hospitals of the French Community of Belgium.

For all of the women :

- Vaginal and anal specimens at 35-37 weeks gestation
- Vaginal specimen soon after admission for delivery

Collection and culture of specimens

- Lower third of the vagina and beyond the anal sphincter
- Prenatal screening specimens : collection and transport system Culturette®, Becton Dickinson
- Delivery specimens : duplicate swabs in one collection and transport system Culturette II®, Becton Dickinson
- All specimen transported at room temperature, stored maximum 24 h at 2-8°C and processed within 24 h of collection
- All specimens inoculated onto Colistin-Nalidixic Acid sheep blood agar (CNA), then submersed in selective enrichment broth (LIM, Becton Dickinson) subsequently subcultured onto CNA agar plate. Incubation 48 h at 37°C + CO₂. GBS identification confirmed by an agglutination serogrouping test and quantified on primary culture plate as 1+ to 4+ using standardized criteria.

Rapid screening test for GBS

Strep B OIA® test (BioStar, Boulder, Co) performed according to manufacturer on one paired-swab of all delivery vaginal specimens

Analysis

Rates of colonization calculated on the basis of the results of culture. Sensitivity, specificity, positive and negative predictive values of both prenatal screening culture (combined vaginal and anal specimens) and rapid intrapartum screening test (vaginal specimen) : estimation by comparing results with intrapartum vaginal culture results.

REFERENCES

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RESULTS

Rates of detection of GBS colonization among 531 pregnant women

Timing	Vaginal specimen	Anal specimen	Combined Vaginal - anal specimens
	Number of positive culture (%)		
35-37 Weeks	74 (13.9)	80 (15.1)	87 (16.4)
At delivery	71 (13.4)		

Performed at delivery, Strep B OIA tests were positive for 47 pregnant women (8.9 %).

Sensitivities for prenatal screening and Strep B OIA, respectively 69 % (58-85%) and 62 % (33-85 %) were not significantly different.

Sensitivity, specificity and predictive values of prenatal screening culture and Strep B OIA for the detection of GBS vaginal carriage from 531 pregnant women - Percent (No)

Method of detection	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
Prenatal screening culture	69 (49 /71)	91.7 (422 /460)	56.3 (49 /87)	95 (422 /444)
Strep B OIA at delivery	62 (44 /71)	99.3 (457 /460)	93.6 (44 /47)	94.4 (457 /484)

Strep B OIA test sensitivity versus GBS culture density of direct plating onto CNA agar

Sensitivity	Semi-quantitative GBS culture result				
	4+	3+	2+	1+	LIM alone
%	93	75	57	47	29
(No.)	(14 /15)	(6 /8)	(12 /21)	(9 /19)	(2 /7)

DISCUSSION

- To prevent neonatal GBS disease, current recommendations* could be improved by using a reliable, sensitive, easy to use rapid test performed at admission for delivery. It should be cost-effective and would lead to prevention of a highest percentage of cases.
- As in other European countries, in this Belgian study, the prevalence of colonization, is lower than in North America.
- In our study, predictive values of prenatal screening GBS cultures as for Strep B OIA test were lower than expected. But this study was conducted in real world (6 hospital laboratories) and not in research lab. Nonetheless Strep B OIA in identifying GBS carriers at time of delivery, was at least comparable to prenatal screening cultures and its higher positive predictive value would lead to a significant reduction of useless IAP ($p < 0.001$).
- Strep B OIA are available within 30 minutes, but a close compliance to timing of the different steps is required; it could be a limitation to its use in a busy emergency laboratory.

CONCLUSIONS

To identify GBS carriers at time of delivery, Strep B OIA test performed intrapartum is equally sensitive to prenatal screening cultures and would lead to a highly significant reduction of useless IAP.

- Strep B OIA is ideal when prenatal cultures are not available
- It should help for compliance to prevention strategies and should facilitate treatment
- As for prenatal screening GBS cultures, sensitivity and specificity varied widely from lab to lab
- Before choosing a rapid test-based strategy, a local validation of technical performers should be done by proficiency testing.