Comparison of Starplex and Copan vaginal and rectal swabs for the detection of group B streptococci (GBS) in pregnant women.

M. MYERS, BETTY C. CATANZARITI, LISA NORTON, S. BURN, L. STOAKES, R. NATALE, M. A. JOHN, Z. HUSSAIN

Department of Microbiology, London Health Sciences Centre, and Obstetrics and Gynecology St. Joseph's Health Centre, London, Ontario.

Abstact:

Objectives: Screening of all pregnant women for GBS is recommended because the organism can be vertically transmitted. GBS causes severe invasive disease in newborns and is associated with a 4% case-fatality. The IDI-Strep B (Real-time PCR) is the first non-culture test that meets the performance criteria recommended by CDC-guidelines. We compared Starplex and Copan swabs with Stuart liquid transport media on a sponge to collect vaginal/rectal specimens from pregnant women for GBS detection by the IDI-Strep B test.

Methods: At the time of delivery, vaginal/rectal specimens were collected using Starplex and Copan swabs and paired swabs were sent to the Department of Microbiology. Each swab was vortexed with sample preparation buffer. Five hundred microlitres of sample buffer from the Copan swab was added to 5 ml of selective Todd Hewitt broth (TH) and $50 \,\mu\text{L}$ of each sample broth was added to lysate buffer. Lysate buffers were used to prepare master mix to perform IDI-Strep B test using the Smart Cycler. TH was incubated overnight and sub-cultured onto a Columbia agar plate with 5% sheep blood (BA). Any growth on BA was screened for the presence of GBS using standard methods. **Results:** 173 women were recruited. Forty of these, were positive for GBS by culture. Thirty-six of 40 specimens collected by Copan swabs were positive by PCR. Two additional Copan specimens that were culture-negative were positive for GBS by Realtime PCR. Of culture positive specimens, Starplex PCR test was positive in only 33 specimens but 8 of culture-negative specimens were also positive by PCR. Conclusions: Copan swabs are recommended by the manufacturer of the IDI-Strep B kit and have been validated. Starplex swabs have recently marketed swabs to be used to collect specimens to be tested by realtime PCR. Specimens collected by either swab failed to detect GBS in all culture and PCR positive specimens. However, Starplex swabs were equal to Copan swabs for the detection of GBS by the IDI-Strep B kit.

Introduction:

Colonization of pregnant women with *Streptococcus agalactiae* (GBS) is common, with 10 to 30% of pregnant women harboring the organism in their rectum and or vagina. Transmission of GBS to their baby during childbirth may result in septicemia, meningitis and other systemic infection. A small number of neonates acquire the organism from their colonized mothers primarily after the onset of labor or membrane rupture. It has been observed that antibiotic prophylaxis given to GBS-positive women during labor can prevent transmission of the organism from the mother to the child thus preventing early onset GBS disease in most cases.

New evidence suggests that a culture based screening approach is superior to risk based screening approach for prophylaxing GBS-positive mothers and for the prevention of early onset GBS disease in newborns. Based on this evidence, the CDC recommends that all pregnant women should be screened for colonization at 35 to 37 weeks gestation. Recently a real time PCR method for GBS colonization detection, IDI-Strep B test has been marketed by Infectio Diagnostic Inc. (IDI) Sainte Foy, Quebec. In a multicentre study, this method was shown to detect at least 94% of GBS colonized pregnant women. It is important that swabs and transport media used are free of PCR inhibitors and do not affect amplification. IDI recommends the use of the Copan Venturi Transystem ® (141C, catalogue no. IDI-2002-002) for specimen collection and transport. The Copan Venturi Transystem consists of a swab and a Stuart medium-soaked sponge. The manufacturer of the IDI Strep B test has validated these swabs and media. Recently, Starplex has also marketed a similar collection and transport system, Starswab II. We compared the Starswabs II transport system with the Copan Venturi Transystem for the collection and transport of specimens from pregnant women. Specimens were processed using the IDI strep B test to detect GBS colonization.

Material and Methods:

Ethics Board approval and consent of participating patients were obtained. At the time of labor two vaginal/rectal specimens were collected using Copan and Starplex swabs. Swabs were transported to the Department of Microbiology. On their arrival swabs were put in two different preparation buffer tubes supplied with the IDI Strep B test. The IDI strep B test was performed on specimens collected by each swab system in a parallel manner. In addition, 500 μ l of the preparation buffer of the Copan swab was transferred to a 5 ml selective Todd-Hewitt broth containing 5 μ g/ml of gentamicin and 15 μ g/ml of nalidixic acid. After overnight incubation, the broth was sub-cultured onto Columbia agar supplemented with 5% sheep blood (Oxoid). The plates were incubated for 18 to 24 hours under 5% CO₂. The presence of GBS was determined using routine methods.

Results:

Specimens were collected from 173 pregnant women. Forty-eight women were culture or PCR were positive (27.7%). The details of the results of each method are shown in table 1.

| | # of RT PCR – | # of RT PCR- | # of RT PCR- | # of RT PCR- |
|----------------|----------------|----------------|----------------|----------------|
| | positive women | negative women | positive women | negative women |
| | (COPAN) | (COPAN) | (STARPLEX) | (STARPLEX) |
| # of Culture- | 36 | 4 | 33 | 7 |
| positive women | | | | |
| # of culture- | 2 | 131 | 8 | 125 |
| negative | | | | |
| women | | | | |

In total 48 women were positive for GBS. Starplex RT PCR and Copan RT-PCR correctly identified 85.4% and 79.2% of women carriers respectively. Preparation buffer subcultures were positive in 83.3% of GBS carrying women.

Conclusions:

The use of non-ihibitory swabs and transport media is crucial for the collection of specimens for PCR. The IDI-Strep B test is FDA approved for the detection of GBS colonization in pregnant women. The manufacturer has validated and recommends the use of the Copan Venturi Transystem for specimen collection and transport. In our hands the Starswab II collection and transport system gave similar results to the Copan system. Although the number of specimens included in the study was relatively small, both collection and transport systems appeared to give equally reliable results.