Evaluation of StrepB Carrot Broth versus Lim Broth for Detection of Group B Streptococcus Colonization Status of Near-Term Pregnant Women*\textsuperscript{v}

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The performance of StrepB Carrot Broth (SCB) versus group B Lim broth (LIM) for detection of group B streptococcus (GBS) colonization status in near-term pregnant women (35 to 37 weeks of gestation) was evaluated. Dually collected vaginal/rectal swabs from 279 women enrolled from a single large maternity clinic were analyzed. Fifty (18%) women were colonized by GBS according to both methods. SCB had excellent diagnostic performance compared to LIM, with sensitivity, specificity, positive predictive value, and negative predictive value of 92%, 100%, 100%, and 98.3%, respectively. Improved diagnostic efficiency due to direct reporting of GBS cases based on an orange color change in the SCB decreased overall labor and material costs.

Group B streptococcus (GBS) is the most common cause of early-onset neonatal sepsis in developed countries (5). Early-onset disease (0 to 6 days of life) is acquired intrapartum from mothers with vaginal/rectal colonization with GBS (9, 10, 12, 13, 15, 17). Maternal GBS colonization rates range from approximately 10% to 40% in developed countries, with an estimated rate of 20% in near-term pregnant women in the Calgary Health Region (CHR) (4–6). Studies have shown that intrapartum administration of antibiotics reduces neonatal transmission of GBS, thereby preventing early-onset disease (8, 12, 14, 15). Laboratory detection of GBS colonization status in near-term pregnant women is therefore important for the selective prescription of antibiotic prophylaxis at delivery.

The Centers for Disease Control and Prevention (CDC) (3, 8, 14) and other medical organizations (1, 2, 16) have published consensus guidelines on the prevention of early-onset neonatal GBS disease. Two prevention strategies have been described, a risk-based approach (based on maternal factors with or without known GBS colonization) and a screening-based approach (based on a combination of risk factors and GBS colonization). Because recent evidence showed a protective effect of prenatal GBS screening compared with the risk-based approach, new guidelines were set out by the CDC, recommending universal prenatal culture-based screening for vaginal/rectal colonization of all pregnant women at 35 to 37 weeks of gestation (or sooner if membrane rupture occurs), with intrapartum chemoprophylaxis offered to the carriers (3, 8). Laboratory confirmation of GBS colonization requires collection of a vaginal/rectal swab that is cultured using a group B selective broth such as Lim broth (LIM; Todd-Hewitt broth with colistin and nalidixic acid) and incubated for 24 h, with subculture onto blood agar and phenotypic identification of potential beta-hemolytic GBS colonies (3).

Since our high-volume laboratory performs ~1,200 GBS screen cultures on vaginal/rectal swabs each month, it was of interest to further improve the diagnostic performance and efficiency of this method. Inclusion of direct plating of swabs onto selective agar media had been implemented in our laboratory since it decreased the test turnaround time (6). Since most GBS strains are hemolytic (~80%), most are detected by direct plating and growth on 5% sheep blood agar, but the remainder can be detected only after subculture and further biochemical testing. Newer commercial molecular and nonmolecular test systems for detection of GBS in vaginal/rectal specimens that have improved sensitivity, decreased test turnaround time, and increased test efficiency and that are easier to perform have recently been marketed (7). This initial evaluation compared StrepB Carrot Broth (SCB) (Hardy Diagnostics Inc., Santa Maria, CA) to LIM for the selective enrichment and detection of GBS in near-term pregnant women. SCB is a modification of Granada media (Hardy Diagnostics) that detects GBS based on a GBS hemolytic strain’s unique ability to react with substrates (i.e., starch or proteose peptone) present in the broth. A positive reaction produces an orange, red, or brick red pigment that is visible to the naked eye in as little as 6 h. No prior studies using a design involving a collection of pairs of vaginal/rectal swabs to perform a true side-by-side comparison of LIM versus SCB have been reported.

Near-term pregnant women (i.e., 35 to 37 weeks of gestation) were enrolled with consent that received routine obstetrical care at a single large maternity clinic in the CHR (Maternity Care Clinic, Sunridge Professional Building, Calgary, Alberta, Canada). Duplicate vaginal/rectal swabs were physician collected using Copan swabs in liquid Amies transport tubes and transported within 4 to 6 h to the laboratory. One swab was inoculated onto a blood agar plate plus LIM, while SCB was inoculated using the other swab. Plates were always inoculated first, followed by insertion and subsequent incubation of one of the swabs in each type of broth. Cultures were...
incubated for 18 to 24 h at 35°C. GBS colonies growing on 5% sheep blood agar were identified by the presence of typical colony morphology and biochemical reactions; GBS is beta-hemolytic, and the group B carbohydrate latex typing is positive (Prolab Strep; PML Microbiologicals, Wilsonville, OR). LIM was subcultured to a 5% sheep blood plate, incubated for another 18 to 24 h at 35°C, and analyzed for the presence of GBS using the same methods as for the primary plate culture. All SCB cultures were read as positive if a visible color change to orange or red from colorless occurred. All SCB cultures were also subcultured onto 5% sheep blood agar, incubated for another 18 to 24 h at 35°C, and analyzed for the presence of GBS using the same methods as for the primary plate culture. Diagnostic efficiency was determined by recording the resources utilized to perform each test method (labor and supplies). Resource utilization costs from the study period were extrapolated to estimate the projected costs of routine utilization of either medium during a routine testing month in order to project the annual resource impact of implementing SCB. All costs were calculated in Canadian dollars. Labor costs were calculated based on the current hourly rates paid by Calgary Laboratory Services (CLS) to medical laboratory assistants and medical laboratory technologists. Supply costs included the Canadian goods and services tax. Data were entered into an Excel (version 3.0) spreadsheet (Microsoft Corporation, Seattle, WA) and analyzed using Analyze-it software (Microsoft Corporation, Seattle, WA) by standard statistical methods.

A total of 279 women were enrolled from a single large maternity clinic in the CHR. The median age of the enrolled women was 27.6 ± 5.1 years. Fifty (18%) women were colonized by GBS. Table 1 shows the performance data for SCB versus LIM. All positive SCB cultures were confirmed by subculture to have GBS present. Of the 233 colorless SCB cultures, 4 grew a nonhemolytic GBS on subculture while the remaining 229 were confirmed to be negative. LIM detected 45 GBS cases. Five LIM results were initially discordant with the SCB result: LIM was initially negative, but GBS was isolated from the SCB. The results were resolved by a second inoculation of the original specimen swabs to LIM, where subculture confirmed the presence of GBS in all five cases. No false-positive tests occurred using either broth. SCB had excellent performance compared to LIM, with a sensitivity of 92%, specificity of 100%, and negative predictive value (NPV) and positive predictive value (PPV) of 100% and 98.3%, respectively. The overall efficiency of SCB was 98.6%.

Table 2 lists the estimated component costs of performing GBS vaginal/rectal cultures using either type of broth as our routine method during a typical month. Routine utilization of SCB would decrease monthly labor costs by 25.4% (equivalent to 0.67 full time equivalent), while overall material costs would decrease approximately 40% even though SCB is more expensive than LIM. Implementation of SCB is projected to decrease annual service costs in our regional microbiology operation by 38% and result in an annual saving of more than $80,000.

This study is the first clinical evaluation of SCB for the routine detection of GBS from dually collected vaginal/rectal swabs in a high-volume laboratory setting. Few other studies have evaluated SCB for detection of GBS colonization in near-term pregnant women. A recent multicenter trial compared LIM and SCB for detection of GBS from a single vaginal/rectal swab, and the performance of SCB was excellent compared to that of LIM with subculture onto blood agar (11), but an economic analysis wasn’t done. A recent Canadian study compared several culture methods for the detection of GBS from 200 vaginal/rectal swabs collected from near-term pregnant women (E. Thomas, presented at the 2006 Meeting of the Association of Medical Microbiology and Infectious Disease, Canada, Victoria, British Columbia, Canada). Culture using direct plating onto tryptic soy agar with 5% sheep blood and trimethoprim-sulfamethoxazole, LIM with subculture onto blood or Granada media (Hardy Diagnostics, Santa Clara, CA), and SCB (orange color change) were compared. SCB media with an orange color change had the best overall performance, with sensitivity, specificity, PPV, and NPV of 92%, 100%, 100%, and 98%, respectively (E. Thomas, presented at the 2006 Meeting of the Association of Medical Microbiology and Infectious Disease, Canada, Victoria, British Columbia, Canada). SCB also demonstrated excellent performance compared to real-time PCR (Cepheid Smart Cycler) in one recently reported study (7).

The improved diagnostic performance and efficiency of SCB would allow more appropriate management of GBS-colonized near-term pregnant women. Because all visually positive SCB cultures (i.e., orange or red) could be immediately reported (Fig. 1), this method improved diagnostic efficiency by dra-

### Table 1. Performance of SCB compared to LIM for GBS detection

<table>
<thead>
<tr>
<th>SCB result</th>
<th>No. of samples with LIM result of:</th>
<th>Total no. of samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Positive</td>
<td>46</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>4</td>
<td>229</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>229</td>
</tr>
</tbody>
</table>

*Sensitivity, 46/50 (92%); specificity, 229/229 (100%); PPV, 46/46 (100%); NPV, 229/229 (98.3%); efficiency, 275/279 (98.6%).

### Table 2. Comparison of CLS study costs for using SCB versus LIM for GBS detection

<table>
<thead>
<tr>
<th>Component of analysis</th>
<th>Cost for:</th>
<th>Immediate effect on cost of change to SCB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Media</td>
<td>$1,545.75</td>
<td>$927.45</td>
</tr>
<tr>
<td>Total materials</td>
<td>$1,832.00</td>
<td>$4,189.93</td>
</tr>
<tr>
<td>No. of tests/mo</td>
<td>1,145</td>
<td>1,145</td>
</tr>
<tr>
<td>Total monthly cost</td>
<td>$3,362.75</td>
<td>$10,244.43</td>
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<tr>
<td>Total annual cost</td>
<td>$40,353.00</td>
<td>$122,933.16</td>
</tr>
<tr>
<td>Total annual labor</td>
<td>0.23 FTE</td>
<td>0.39 FTE</td>
</tr>
</tbody>
</table>

*Total material costs included the cost of media.

*MLT, medical laboratory technologists/medical laboratory assistants.

*Total costs include the Canadian goods and services tax, but not shipping and handling; costs were calculated based on a volume of 1,145 specimens per month and a positivity rate of 17%.

*Projected annual resource savings extrapolated from the monthly labor/material savings.

*Monetary values are in Canadian dollars. FTE, full time equivalent.

↑, cost increase; ↓, cost decrease.
matically reducing the number of subcultures that needed to be done. The significant projected annual resource savings (~$80,000) could be utilized to perform other laboratory procedures. Proportional savings based on annual vaginal/rectal GBS cultures would occur in other laboratory settings since the test volumes remain constant throughout the year with little seasonal variability. Further studies should confirm these findings in a larger number of cases in different laboratory settings and determine the performance of SCB compared to more-sensitive non-culture-based methods of GBS detection.

CLS supported this study.

CLS Finance reviewed the costing analysis. Med-Ox Canada (Ottawa, Ontario) provided the SCB media from Hardy Diagnostics (Santa Clara, CA).

REFERENCES


18. Reference deleted.