Comparison of Two Prevention Strategies for Neonatal Group B Streptococcal Disease

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Background: **Neonatal group B streptococcal disease is a serious infection, causing more than 2,000 cases of sepsis annually. The Centers for Disease Control and Prevention has recommended two alternative strategies to prevent infection, but few data directly compare the two in terms of intrapartum antibiotic administration, protocol feasibility, newborn laboratory evaluation, and costs.**

Methods: **We collected data on intrapartum antibiotic administration, protocol compliance, newborn laboratory evaluation, and maternal-newborn length of stay for 347 mother-infant pairs in a family practice residency maternity service. During the first study period, laboring women were managed under the screening strategy, and during the second study period, laboring women were managed under the risk factor strategy.**

Results: **Of those women who qualified for antibiotic prophylaxis, only 28% of women in the screening group and 47% of women in the risk factor group actually received the recommended two or more doses of intrapartum antibiotics. Ninety-one percent of women in the screening group had prenatal cultures done appropriately. Newborns in the screening group had an increased risk of having a complete blood count (OR = 1.35, 95% CI 1.01, 1.80). There was no difference between groups in maternal or newborn length of stay.**

Conclusions: **A minority of laboring women in either strategy received the recommended doses of intrapartum antibiotics. Feasibility of obtaining prenatal screening cultures is high. Although newborn laboratory testing increased with the screening strategy, overall costs and length of stay were comparable. (J Am Board Fam Pract 2002;15:272–6.)**

Neonatal group B streptococcal disease is a serious infection, with more than 2,000 cases reported in 1998 in the United States.[1] A continuing dilemma in prevention and management is choosing of one of two acceptable protocols. A decision whether to administer intrapartum antibiotics must be made for every laboring patient. Consensus guidelines published by the Centers for Disease Control and Prevention (CDC), the American College of Obstetricians and Gynecologists (ACOG), and the American Academy of Pediatrics (AAP) in 1996 recommend two acceptable prevention strategies involving administration of intrapartum antibiotics.[2] One strategy (screening) is based on prenatal screening cultures at 35 to 37 weeks' gestation, and the other strategy (risk factor) is based on intrapartum risk factors.

Although there is no direct evidence comparing the two strategies, the screening-based strategy is thought to be slightly more efficacious based on decision analyses using estimates from the literature.[3,4] One recent study found no difference in efficacy.[5] Because of the low prevalence of neonatal group B streptococcal disease, direct comparison studies of efficacy are not feasible, as they would require about 100,000 patients to show a difference in patient outcomes between the two groups.[6]

When compared with the risk factor strategy, the screening strategy, although possibly more effective, is estimated to be more difficult to comply with, to expose more women and babies to antibiotics, to lead to an increased number of newborn laboratory evaluations, and to cost more.[3,7,8] In the absence of published comparisons of the two strategies, providers are left with no definitive guidance and questions of whether the possible (but unproved) increased efficacy of the screening strategy is worth the increased exposure to antibiotics, inconvenience, and added laboratory testing.

The objective of our study was to compare the two strategies based on the rates of intrapartum-newborn antibiotic administration, protocol adherence, and amount of newborn laboratory testing in

a family practice residency maternity service. A secondary analysis was performed to compare costs indirectly by determining length of stay for mothers and newborns and hospital charges for newborns.

The impetus for the study arose when we perceived that maternal intrapartum antibiotic usage and newborn laboratory evaluation increased after we adopted the screening strategy in July of 1996, compared with our previous use of the risk factor strategy. The CDC estimates that 28% of mothers would receive intrapartum antibiotics with the screening strategy and 18% would receive intrapartum antibiotics with the risk factor strategy.[3] We hypothesized that compliance would be more difficult with the screening strategy, because screening must done in a restricted time frame and results must be available at the time of delivery. In addition, because more mothers would be receiving intrapartum antibiotics with screening, we postulated that newborn laboratory evaluations for sepsis and antibiotic administration would increase based on an algorithm included in the consensus statement for management of newborns if maternal intrapartum antibiotics were administered.[2,7] This same algorithm might also lead to an increased length of stay for newborns based on a recommended minimal 48-hour stay if mothers received intrapartum antibiotics. This information could be useful for other practices in deciding which prevention strategy to implement for their maternity patients.

Methods
Setting
Data for the study were obtained from births occurring in the Lancaster, Pa, family practice residency maternity service during an 11-month period. The family practice residency is the only residency program in a 400-bed community teaching hospital. It has been in existence since 1969 and currently has 39 residents, 13 in each of the 3 years. We average 530 deliveries per year on the family practice residency maternity service, which is about one fifth of the total deliveries in the hospital. All deliveries on the service are performed by family practice residents and attended by family practice faculty, with obstetric consultation as needed for cesarean sections or high-risk situations. Seven of 11 full-time faculty members include obstetrics in their practice. One faculty member has completed an obstetric fellowship. The faculty also includes a board-certified obstetrician who serves as a consultant for high-risk patients.

Sample
Data were collected from delivery logs, chart reviews, and medical record reports from April 1998 to March 1999. Data collection was grouped by two periods. In the screening group, women who gave birth from mid-April through August 1998 had their pregnancies managed under the screening strategy. A single vaginal-rectal swab for group B streptococcus culture (enhanced-growth medium) was obtained after 35 weeks' gestation, and laboring patients were treated with intrapartum antibiotics if the culture was positive. In the risk factor group women who gave birth from mid-October 1998 through mid-March 1999 had their pregnancies managed without prenatal screening for group B streptococcus. Laboring patients were treated with intrapartum antibiotics if there were risk factors according to the consensus protocol.

A 6-week transition period (September through mid-October) was used to allow screened women to give birth. During the transition period, all providers were made aware of the change to a risk-based strategy through a noon conference and with frequent e-mail reminders. Births were determined to be ineligible for the study for two reasons.[1] Women who gave birth before 37 weeks were eliminated from the analysis, because they would receive the same care under both protocols.[2] Women who underwent elective cesarean sections were not included because their treatment would be independent of either strategy. Women undergoing nonelective cesarean sections were included.

A total of 378 mother-infant pairs were evaluated. Twenty-nine patients met exclusion criteria, 18 for preterm deliveries and 11 for elective cesarean deliveries. A total of 347 mother-infant pairs remained eligible for analysis, 171 in the screening group and 178 in the risk factor group. For the secondary analysis on length of stay, women undergoing cesarean section for any indication were excluded, because their hospital stay would be independent of protocols for group B streptococcus. An additional 38 women were excluded by this criterion, leaving a total of 309 eligible for this analysis: 154 in the screening group and 155 in the risk factor group.

Family practice residents, with attending coverage by 16 pediatricians from three private groups,

Table 1. Patient Characteristics, by Prenatal Screening (n = 171) and Risk Factor (n = 178) Groups.

Characteristics	Prenatal Screening Group	Risk Factor Group
Maternal age, y	22.3	22.1
Gestational age, wk	39.8	39.6
Birth weight, g	3,329	3,262
Primiparous, %	21.4	39.0

Table 2. Mother's Compliance with Intrapartum Antibiotic Administration, by Prenatal Screening (n = 43) and Risk Factor (n = 34) Groups.

Doses of Antibiotics	Prenatal Screening Group* No. (%)	Risk Factor Group No. (%)	P Value
0	8 (19)	1 (3)	.05
1	23 (53)	17 (50)	
2 or more	12 (28)	16 (47)	

*Number with positive screening results.

managed newborn care (family practice faculty do not provide newborn nursery care as a result of a contractual teaching agreement with local pediatricians). All pediatricians were board certified. Neither the hospital nor the pediatric groups followed a protocol for management of newborns at risk for group B streptococcal disease. Diagnostic evaluation and treatment were at the discretion of the attending pediatricians. Although 15% of the residents in the program were aware of the study, none of the pediatricians were informed of the project.

Data Analysis

To assess compliance, we collected data on the number of doses of antibiotics that eligible women received during their labor for both groups and the percentage of women screened in the screening group. We also collected data for outcomes of newborn complete blood counts and blood cultures, and the number of babies receiving antibiotics. Additionally, data were also collected for secondary outcomes that included maternal length of stay, newborn length of stay, and newborn hospital charges. Statistical analysis was performed using SPSS, version 7.5. Continuous outcome measures were analyzed using the independent t test for dependent variables. Discrete outcome measures were analyzed using the chi-square test.

Results

The patient characteristics are listed in Table 1. The two groups are comparable except for a higher percentage (39.0% vs 21.4%) of primiparous women in the risk factor group. No cases of neonatal group B streptococcal sepsis were diagnosed during the study period.

Table 2 provides data on number of antibiotic doses for women who met protocol guidelines for intrapartum antibiotic administration. The overall difference in obtaining intrapartum antibiotics between the groups approached statistical significance ($P = .05$). The analysis was done with a single chi-square statistic for the six cells in the table.

The major difference between the groups was in the number of eligible women who received no doses of antibiotics. Women in the screening group (8 patients) were more likely to receive no doses of antibiotics when compared with the risk factor group (only 1 patient). This was primarily due to lack of time; of the 8 women, 6 gave birth rapidly with an average time of 43 minutes after admission. The other 2 women in this subset were protocol violations; the providers were unaware of the women's group B streptococcal culture results even though the results were in the medical records. A large percentage of women in both groups received only one dose of antibiotics. Again, lack of time was the reason. In both groups, labor progressed too quickly to administer a second dose of antibiotics for the 40 women involved in this subset (23 in the screening group and 17 in the risk factor group). A minority of women in both groups received the recommended two or more doses, 28% in the screening group and 47% in the risk factor group. In the risk factor group, 73% (25 of 34) of women received treatment for the indication of ruptured membranes for longer than 18 hours.

Compliance with obtaining prenatal screening cultures was high. Ninety-one percent of the women in the screening group had prenatal cultures for group B streptococcus done at the appropriate time, and results were available at the time of labor. The rate of group B streptococcal colonization in our population was 25%.

Table 3 displays the results on the primary outcomes comparing laboratory evaluation of newborns and antibiotic usage in newborns and laboring women. There was an increased odds of newborns having a complete blood count ordered

Table 3. Percentage of Newborns with Complete Blood Count (CBC) and Blood Culture, and Mothers and Newborns with Antibiotic Use, by Prenatal Screening (n = 171) and Risk Factor (n = 178) Groups.

Characteristic	Prenatal Screening Group (%)	Risk Factor Group (%)	P Value	Odds Ratio (95% CI)
Newborns with ≥1 CBC	41	30	.039	1.35 (1.01–1.80)
Newborns with a blood culture	26	21	.274	1.24 (0.84–1.82)
Mothers receiving intrapartum antibiotics	20	19	.930	1.08 (0.95–1.15)
Newborns receiving antibiotics	11	11	.970	1.00 (0.93–1.08)

using the screening strategy (OR = 1.35, 95% CI 1.01, 1.80). The percentages of newborns having blood cultures drawn, of newborns receiving antibiotics, and of mothers receiving antibiotics were not different between the two study groups. Table 4 provides data on the secondary outcomes of maternal and newborn length of stay and newborn hospital charges. No differences were detected between the study groups.

Discussion

Time constraints preventing the administration of two doses of antepartum antibiotics were a major reason for noncompliance with neonatal group B streptococcal infection prophylaxis. This finding concurs with other research findings.[9] Lack of time seems to be more pronounced with the screening strategy because of the higher likelihood of women with a reason to receive antibiotics being admitted in advanced labor. In other words, using the screening protocol, 25% of the women admitted in advanced labor will have a positive prenatal culture and require antibiotics. In the risk factor protocol, few full-term patients arriving in advanced labor would have an indication for antibiotics. That is, there would be few patients with a fever or whose membranes had ruptured more than 18 hours earlier (the two most common indications for antibiotics) arriving in advanced labor. The higher percentage of multiparas in the screening group probably contributed to the increased number of

women in advanced labor. These data provide a real-life glimpse of what physicians can expect regarding full-term patients if they implement either strategy in their practice.

That no cases of group B streptococcal disease occurred is also of interest, underscoring that serious disease is quite rare. It will take months or years in a typical practice before either strategy makes a difference with a clinical birth outcome.

In terms of adherence to the protocol, the physicians in our program did well at prenatal screening for group B streptococcal disease. The 91% screening rate with culture results available at the time of labor compares favorably with other research findings.[10] Perhaps the ability to establish and implement protocols in a closed system such as a residency program contributed to the high rate.

Our study findings agree with previous estimates that the prenatal screening strategy for the prevention of neonatal group B streptococcal disease leads to more newborn laboratory evaluations when compared with the risk factor strategy.[7,8] Newborns in the screening group had a 37% increased chance of having a complete blood count determination during their hospital stay. Many other variables, such as provider preference and differences in the number of sick infants between groups, however, could account for this finding. Our study, in contrast with others, failed to show an increase risk of neonatal blood cultures.[7] In addition to increasing the costs of newborn care, the increase in com-

Table 4. Maternal and Newborn Length of Stay and Newborn Hospital Charges, by Prenatal Screening (n = 154) and Risk Factor (n = 155) Groups.

Characteristic	Prenatal Screening Group	Risk Factor Group	P Value
Maternal length of stay, h	55.2 ± 21.3	53.9 ± 15.4	.54
Newborn length of stay, h	53.5 ± 24.8	52.4 ± 26.8	.71
Newborn charges, $	1,186 ± 1,406	1,061 ± 1,491	.45

Note: Patients undergoing cesarean section or delivered preterm were omitted.

plete blood counts is bothersome to parents based on surveys regarding pediatric laboratory testing in the emergency department setting.[11]

In terms of resource utilization, we found no significant difference in length of stay for mothers and newborns or newborn hospital charges between the groups. We had anticipated that the recommendations from the 1996 consensus guidelines endorsed by the CDC, the AAP, and ACOG would result in longer lengths of stay and increased charges for the prenatal screening group.

There are several limitations to our study. First, because this study compared the two study groups in two different time periods, the clinical staff involved, the norms of newborn care, and other historical influences might account for some of the differences. Second, the study was conducted in a setting without any protocol for management of newborns of mothers receiving intrapartum antibiotics. As mentioned previously, neither the hospital nor attending pediatricians followed any guidelines for laboratory testing or length of stay recommendations. It is possible that more uniform adherence to a protocol such as the one published by the CDC could have led to different results. Additionally, our study was conducted in a residency program. Physician behavior during residency might not accurately reflect behavior in other settings. Finally, as with many studies, reliability of our results is greatly affected by sample size. Although we collected data on 349 mother-infant pairs, only 77 patients (22%) were affected by the protocols for group B streptococcal infection. This small sample size makes drawing definitive conclusions difficult.

In conclusion, we conducted a study in full-term pregnancies comparing the two most widely accepted prevention strategies for early-onset neonatal group B streptococcal disease in a family practice residency program. In concurrence with other research reports, we showed that the effectiveness of either strategy appears to be limited by the difficulty in administering the recommended doses of intrapartum antibiotics before labor is completed. Time constraints caused more problems with the screening protocol. We found a significant increase in the number of newborn complete blood counts with the prenatal screening strategy and a high compliance with obtaining prenatal screening cultures. We conclude that the length of stay for mothers and newborns is not affected significantly by choice of strategy. Overall costs, therefore, did not differ greatly between the two protocols in this small study. This information could prove valuable for other providers when deciding on a prevention approach for neonatal group B streptococcal infection for their maternity service.

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