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ORIGINAL ARTICLE

Analysis of Prevalence and Management of Pregnant Women Colonized with Group B Streptococcus and Outcomes of their Newborns According to the 2010 Centers for Disease Control and Prevention (CDC) guideline

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Streptococcus agalactiae, Neonatal Sepsis, Guideline Adherence.

Abstract

Objective: To evaluate the implementation of the 2010 Centers for Disease Control and Prevention (CDC) guidelines by the obstetrics and neonatology teams of a tertiary public hospital located in Rio de Janeiro, Brazil. **Methods:** This retrospective study included the medical records of pregnant women who underwent vaginal-rectal swabs at the hospital between Nov. 1, 2014 and Oct. 31, 2015. Of the 595 included swabs, 122 were positive for Group B Streptococcus (GBS). After excluding incomplete medical records, malformations, and women who delivered at other hospitals, 85 pregnant women with positive swabs and 92 newborns were included. **Results:** The prevalence of maternal colonization was 20.5%. The time to vaginal/rectal swab collection ranged from 18 to 39 weeks of gestation, with a mean of 34.9 weeks. Thirty-three of the 85 included pregnant women (38.9%) were not properly managed, since in 19 cases delivery occurred within less than four hours of antibiotic administration, and in 14 prophylaxis was not initiated when indicated. Five of the 92 included newborns (5.4%) were not properly managed, mainly due to unnecessary screening for infection; screening was incomplete in one case, since blood culture was not ordered although the guidelines in effect required it. Of the 86 newborns with management considered adequate, 53 (61.6%) had mothers who were also adequately managed. Thirty-three (57.75%) of the newborns managed adequately had mothers submitted to inadequate obstetric management. **Conclusions:** Although the 2010 CDC guidelines for prevention of early sepsis by GBS has been implemented in the hospital, we have detected failures in maternal intrapartum prophylaxis and newborn assessment. Failure to adhere to the established guidelines yields missed opportunities to prevent early-onset GBS sepsis.

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INTRODUCTION

Lancefield Group B beta-hemolytic Streptococcus (GBS or Streptococcus agalactiae) is a gram-positive diplococcus that chronically or intermittently colonizes the vaginal/rectal area. Although most colonized pregnant women are asymptomatic, GBS can cause infection and compromise the amnion, endometrium, or abdominal wall, in addition to causing sepsis and, more rarely, meningitis[1].

Despite measures taken to prevent perinatal sepsis due to GBS since the 1990s, this bacterium remains the leading cause of early-onset neonatal sepsis among newborns[2]. Therefore, screening for maternal colonization between 35 and 37 weeks of gestation is recommended, along with intrapartum antibiotic prophylaxis to decrease the number of cases of early-onset neonatal sepsis. In the United States, the introduction of intrapartum chemoprophylaxis has caused a decline in the incidence of GBS sepsis from 1.8 cases/1000 live births in 1990 to 0.32 cases/1000 live births in 2003[2]. Little has been published in Brazil about maternal and neonatal colonization rates, and few institutions have implemented guideliness or technical recommendations to address the issue[1].

The present study was carried out in a public tertiary referral hospital for high-risk pregnancies and newborns in Rio de Janeiro, Brazil, in which vaginal-rectal swab cultures are routinely performed to detect GBS colonization in pregnant women on prenatal care. In 2007, a similar study conducted in this hospital showed inadequate implementation of prophylaxis and poor adherence to the guidelines recommended by the Centers for Disease Control and Prevention (CDC)[3].

The objective of this study is to evaluate the implementation of the CDC's 2010 Guideline for the Prevention of Perinatal Group B Streptococcus Disease by the obstetrics and neonatology teams of a tertiary referral hospital.

METHOD

This retrospective descriptive cohort study included medical records of pregnant women colonized with GBS on prenatal care at a tertiary referral hospital in Rio de Janeiro, Brazil, in the period from November 1, 2014 to October 31, 2015, and of their newborns. The present is a follow-up to a study performed in 2006 in the same hospital by Costa, 2007, in which the same variables were evaluated, in a time period when the CDC guidelines were being implemented in the hospital. The results of the study by Costa were published and presented to the hospital's obstetrics and neonatology teams.

The procedures described in the present study, including the vaginal-rectal swabs, were conducted entirely at the hospital. The obstetrics service currently follows the 2010 CDC guidelines for perinatal GBS disease prevention. Vaginal/rectal swabs are performed between 35 and 37 weeks of gestation on all pregnant women on prenatal care. The specimens for GBS testing are collected from a single sterile swab of the vagina and rectum during obstetric consultation, which is later sent to the hospital's Bacteriology/Clinical Pathology Department. There, the samples are identified, and each is reconstituted in lyophilized medium in 3 ml of distilled water before seeding and then shaken vigorously to full dissolution. The swab containing the specimen is introduced into a tube with Granada medium, a selective medium for GBS screening and detection. The swab is sectioned and placed in a tightly sealed tube. Specimens are incubated at 35oC (±2) for 18 to 24 hours in aerobiosis. After the first red, incubation is extended for another 24 hours if the medium does not turn over.

In prepartum, the obstetrics service recommends that pregnant women colonized with GBS receive intrapartum antibiotic prophylaxis. The neonatology team also adopts the 2010 CDC guidelines for newborn evaluation, diagnosis, and management.

The study included pregnant women colonized with GBS and their newborns. The women were identified in the prenatal period based on culture records from the bacteriology laboratory. The medical records of mothers and their newborns were extracted from the hospital's information system. Newborns with congenital malformations and genetic syndromes were excluded, along with the ones who were born at other hospitals.

A questionnaire was used to collect data from mothers and newborns. Data points included general information about mothers and newborns, in addition to results of laboratory and supplementary tests carried out at hospital units.

Antibiotic prophylaxis in the intrapartum period was considered for every pregnant woman colonized with GBS. The women received at least one dose of antibiotics in the intrapartum period. The guidelines stipulated that intrapartum antibiotic prophylaxis should occur at least four hours prior to birth. The 2010 CDC guidelines also dictated that women submitted to a cesarean section with an intact sac and no evidence of labor may not receive intrapartum prophylaxis. Incorrect management was defined as not administering antibiotics within the time intervals recommended in the guidelines or as not administering the antibiotic medication proposed for GBS prophylaxis.

Newborns were evaluated based on their medical records and categorized as with proven sepsis, suspected sepsis, or no sepsis. The criteria of Panero et al. and Messer et al. were adopted, in which diagnosis of neonatal sepsis considers at least one or more signs of at least three clinical categories and/or signs of two of these clinical categories plus one or more maternal risk factors, as shown in Table 1[7,8,9].

For purposes of data analysis and storage, a database was created on Epi Info version 3.5.1. The chi-squared test was used to compare between categorical variables and Student's t-test to analyze continuous variables. A p-value of less than 0.05 was considered statistically significant.

The hospital's Research Ethics Committee approved the study and registered it with the National Research Ethics Committee.

RESULTS

During the study period, 595 women had vaginal-rectal swabs performed at our hospital; 122 (20.5%) were positive

Table 1. Diagnostic criteria for infectious syndrome in newborns.

I. Clinical categories:
1. Thermal instability (axillary temperature – Tax < 36.5ºC or Tax > 37.5ºC) at least twice in 24 hours
2. Apnea, bradypnea (respiratory rate – RR < 30 incursions per minute – ipm), moaning, tachypnea (RR > 60 ipm), sternal and subcostal retractions, nasal flaring, cyanosis, increased need for oxygen and ventilator parameters in previously stable newborns on mechanical ventilation
3. Hypotonia and seizures
Irritability and lethargy
4. Gastrointestinal symptoms such as distended abdomen, vomiting, gastric residual, and difficulty accepting food
Idiopathic jaundice
5. Skin pallor, cold and/or sweaty skin, hypotension (mean blood pressure < 30 mmHg or need to administer amines to keep blood pressure above this level), capillary refill time >3 seconds
6. Signs of bleeding, with symptoms suggestive of disseminated intravascular coagulation
Subjective assessment: "a newborn that appears unwell"
II. Maternal risk factors:
1. Fever
2. Proven or suspected urinary tract infection, except in resolved cases treated prior to the start of labor
3. Genital tract infection, chorioamnionitis, fetid amniotic fluid, leukorrhea, genital herpes, papillomavirus, and uterine hypotonia.
III. Hematologic parameters in newborns with suspected infection:
1. Leukocytosis > 20,000/mm^3
2. Leukopenia < 5,000/mm^3
3. Immature to total neutrophil ratio ≥ 0.2
4. Platelet count ≤ 100,000/mm^3
5. Hyperglycemia > 140 mg%
6. Unexplained metabolic acidosis: base excess < -10

for GBS and 471 had a normal microbiota. Two swabs were excluded because they were from non-pregnant women. Thirty-seven of the 122 pregnant women were excluded from the study, one for having incomplete information in her medical records, four because their children were born in other hospitals, and 32 for being pregnant with fetuses with malformations. The study included 85 pregnant women – 78 singleton pregnancies and seven twin pregnancies – yielding a total of 92 newborns (Figure 1).

Age at the time of delivery ranged from 14 to 43 years, with a mean of 30.16 years (standard deviation – SD ± 8.5 years). Regarding race, 46 pregnant women (54.1%) were Caucasian, seven (9.4%) were Black, and 31 (36.5%) were Brown. The mean number of prenatal visits was 10 (SD ± 4.3).

The timing of vaginal-rectal swab collection in colonized pregnant women ranged from 18 to 39 weeks of gestation, with a mean of 34.9 weeks (SD ± 2.5) and median and mode of 36 weeks. More than three quarters (75.3%) of the pregnant women had a vaginal swab done between 35 and 37 weeks of gestation.

Regarding the type of delivery, 44 women (51.8%) had a cesarean section, while 41 (48.2%) had a vaginal delivery. Four women (4.7%) underwent cervical cerclage. As for the time between rupture of membranes and delivery, in nine women (10.6%) the time was 18 hours or longer, in 36 (42.7%) it was less than 18 hours, and 40 (47.1%) went into labor as membranes ruptured.

Forty-six (54.1%) of the 85 pregnant women received intrapartum prophylaxis. Forty-three (93.5%) were given ampicillin and three (6.5%) took cefazolin. Penicillin was not used because it was not available at the hospital.

Maternal management was deemed adequate in 52 (61.2%) cases. Nineteen women (22.4%) were deemed as not receiving adequate management because they were started on antibiotics within less than four hours of delivery. In another 14 pregnant women (16.5%), prophylaxis was not initiated when indicated.

When management was assessed in relation to the type of delivery, we saw that 36 of the 44 women (81.8%) who had a cesarean section were given adequate prophylaxis. Of the eight cases (18.2%) of inadequate management, one (2.3%) was given prophylaxis within less than four hours of delivery and seven (15.9%) were not started on prophylaxis after rupture of membranes. In relation to vaginal deliveries, proper GBS prophylaxis was given in 16 (39%) of 41 cases. In 25 deliveries (61%) management was inadequate, since in 18 (43.9%) vaginal deliveries prophylaxis was started within less than four hours of delivery and in seven (17.1%) prophylaxis was not started when indicated.

Of the 46 pregnant women who received prophylaxis, management was adequate in 27 cases (58.7%). Of the 39 pregnant women who did not receive prophylaxis, management was adequate in 25 cases (64.1%) (Figure 2). One pregnant woman had signs of chorioamnionitis at the time of delivery, and management was adequate in her case.

Ninety-two newborns were included, of which there were 7 pairs of twins. Gestational age ranged from 32 to 42

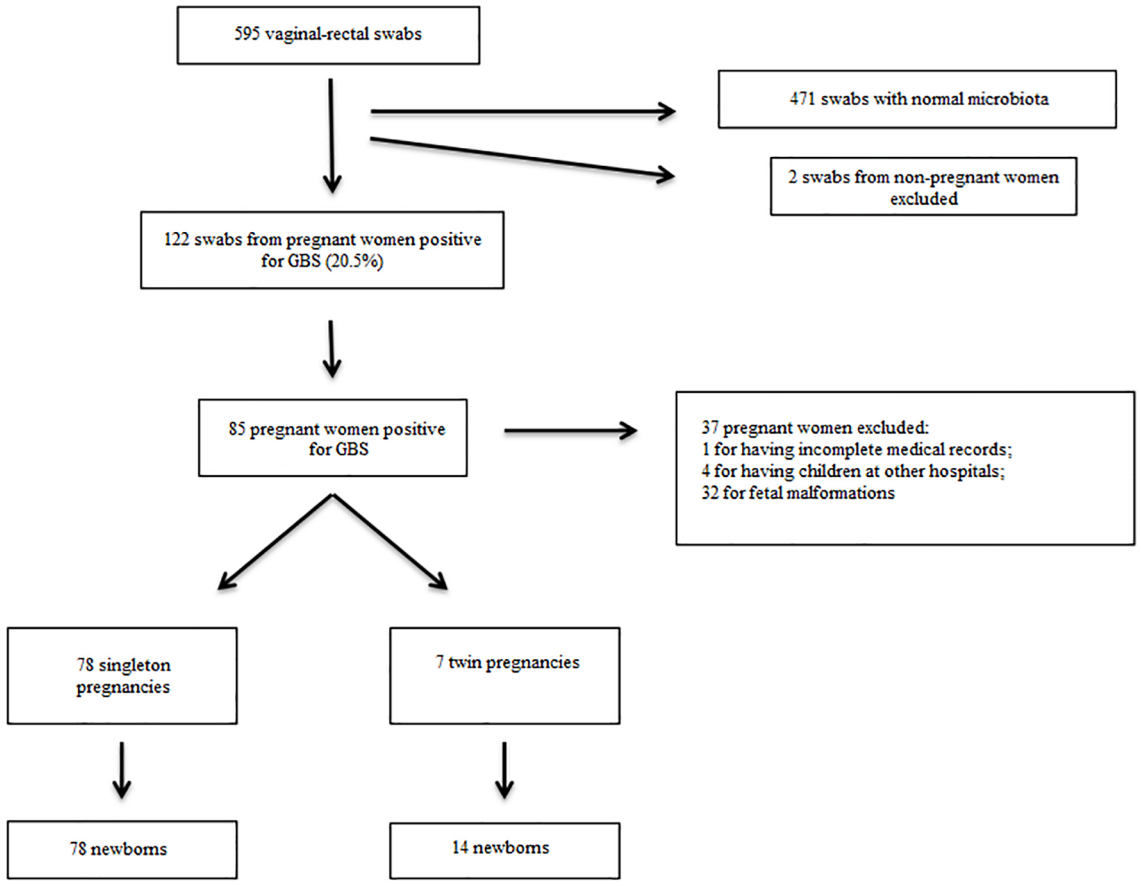


Figure 1. Study population [595 vaginal-rectal swabs | 471 swabs with normal microbiota | 2 swabs from non-pregnant women excluded | 122 swabs from pregnant women positive for GBS (20.5%) | 85 pregnant women positive for GBS | 37 pregnant women excluded: 1 for having incomplete medical records; 4 for having children at other hospitals; 32 for fetal malformations | 78 singleton pregnancies | 7 twin pregnancies | 78 newborns | 14 newborns].

weeks, the mean being 38 weeks and 4 days (SD ± 1 week and 5 days). Fourteen (15.4%) were preterm and 77 (84.6%) were full term newborns.

The mean Apgar scores one and five minutes after birth were 8.3 (SD ± 1.1) and 9 (SD ± 0.5), respectively. The median Apgar scores one and five minutes after birth were 9 and 9, respectively. In the delivery room, eight newborns (8.8%) required neonatal resuscitation; seven (7.7%) received positive pressure ventilation with a mask and one (1.1%) required orotracheal intubation.

Eighty-four newborns (91.3%) remained in the rooming-in unit, while eight (8.7%) were admitted to the Neonatal Intensive Care Unit for various reasons and for presenting with respiratory distress or suspected sepsis.

Screening for infection was performed in 47 (51.1%) of the 92 newborns; ten of them (21.2%) had blood cultures done, all negative. Four newborns (8.5%) had CSF cultures done, all negative for GBS. Screened newborns had 1.8 tests performed on average (SD ± 0.6).

Six of the 92 newborns (6.5%) had signs and symptoms within one week of birth and were treated with ampicillin and gentamicin. Clinical presentations included respiratory distress, hyaline membrane disease, apnea, seizures, early jaundice, and thermal instability. Eight (8.7%) were suspected for sepsis, but none had proven sepsis.

Eighty-six newborns (93.5%) were managed appropriately in accordance with the 2010 CDC guidelines. Five (5.4%) were assessed incorrectly and screened unnecessarily and one (1.1%) did not have a blood culture performed when the guidelines stipulated that a blood culture was required. According to the patient's medical chart, a blood culture was not performed because there were no blood culture bottles available at the hospital. There were no newborns without a screening test when one was indicated. All newborns with suspected sepsis received a correct diagnostic evaluation by the neonatology team.

The analysis of intrapartum maternal management and newborn clinical progress revealed that the five mothers unnecessarily screened for infectious diseases were deemed as receiving adequate management. On the other hand, the newborn submitted to incomplete screening for not having a blood culture done was born from a mother deemed as receiving inadequate management because she was not given prophylaxis when indicated.

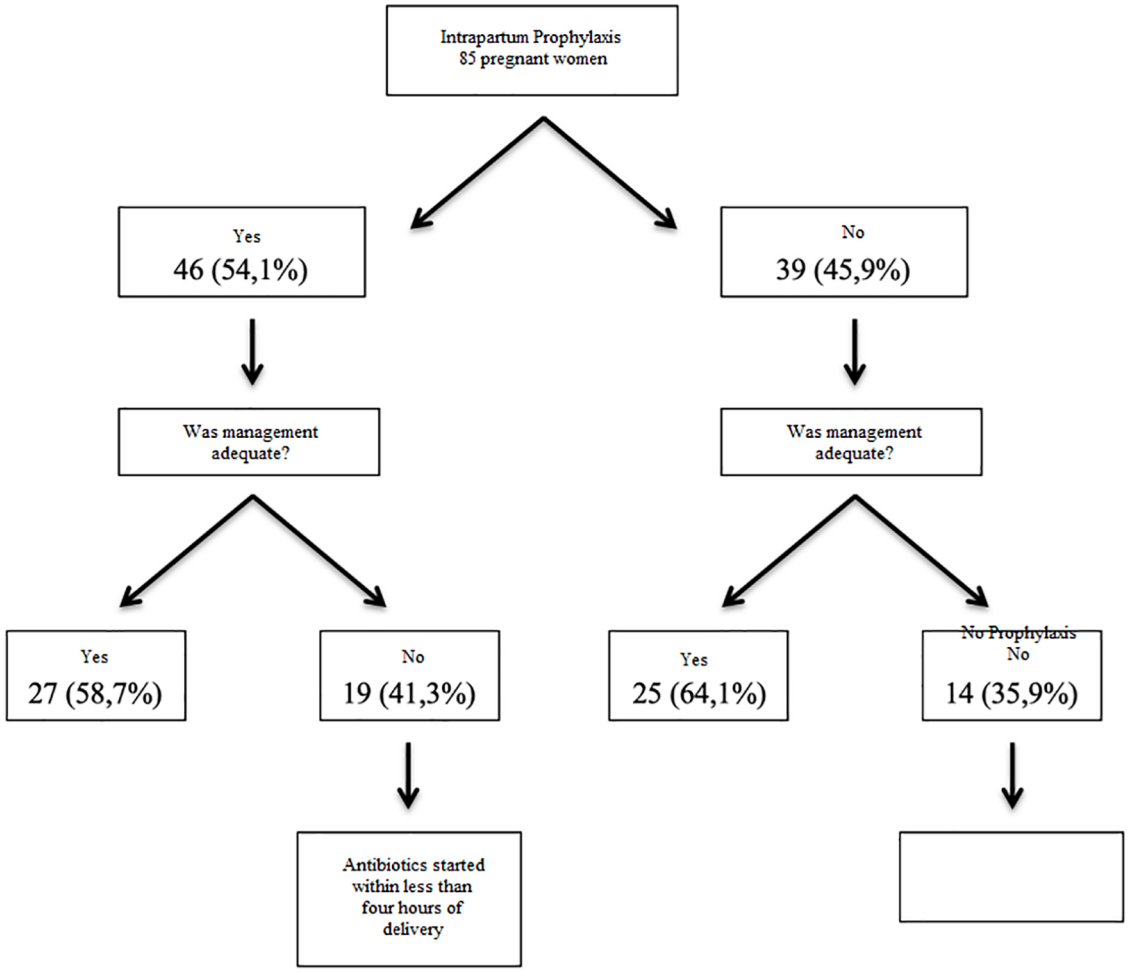


Figure 2. Intrapartum Antibiotic Prophylaxis and Maternal Management. [Intrapartum Prophylaxis – 85 pregnant women | Yes 46 (54.1%) | No 39 (45.9%) | Was management adequate? | Was management adequate? | Yes 27 (58.7%) | No 19 (41.3%) | Yes 25 64.1%) | No 14 35.9% | Antibiotics started within less than four hours of delivery | No Prophylaxis].

Fifty-three of 86 newborns (61.6%) categorized as recipients of proper management had mothers who were also managed adequately. Thirty-three (57.75%) adequately managed newborns had mothers given inadequate obstetric management. In 19 of these mothers, prophylaxis had been performed within less than four hours of delivery, and 14 did not receive prophylaxis when indicated. Fourteen (93.3%) of the newborns whose mothers did not receive prophylaxis when indicated were deemed as recipients of adequate management.

CONCLUSION

Although the rate of maternal GBS colonization has not changed in recent years, its incidence in cases of early neonatal sepsis has decreased significantly with the implementation of intrapartum prophylaxis. The first guideline published by the CDC in 1996 has been updated a few times and used in the management of intrapartum prophylaxis for mothers colonized with GBS and of newborns[6].

In the 1970s, GBS was described as the main pathogen involved in meningitis and sepsis in newborns, which encouraged maternal intrapartum prophylaxis in the following decade and led to a reduction in the occurrence of these diseases[1].

In Brazil, however, there are few studies and recommendations on the subject. The first studies reported a maternal colonization rate of 26% in Porto Alegre and 25% in Florianópolis. In Paraná, colonization was observed in 15% of pregnant women[1]. According to the 2010 CDC guidelines, 10-30% of pregnant women are colonized with GBS in the vagina or rectum between 36-38 weeks of gestational age[2]. In the present study, a prevalence of colonization of 20.5% was found in pregnant women undergoing prenatal care at our hospital, as described in other studies. Nevertheless, the prevalence of maternal colonization depends on the source of the swab, time of collection, and other variables, which may explain differences in prevalence between studies and regions[10].

The CDC places black women at risk of developing sepsis by GBS[2]. In our study, however, 9.4% of the included pregnant

women were black, 36.5% were brown, and 54.1% were white. Costa, 2008 also observed a predominance of white individuals[1]. This is possibly due to the difficulty categorizing people based on skin color in Brazil, since we live in a multiracial nation.

The CDC recommends that screening swabs be performed between 35 and 37 weeks of gestation[2]. However, a rapid test might be preferred to target colonization at the time of delivery. Several tests are being validated, although culture is currently considered the gold standard[11]. We found that 75.3% of the pregnant women included in the study had a swab test done between 35 and 37 weeks of gestation, and that all of them had the colonization test result at the time of delivery, which contributed to the establishment of adequate management.

Fifty-eight percent of the mothers included in our study had cesarean sections. In 2004, a study reported a 41.8% prevalence of cesarean sections in Brazil[12]. The higher proportion of C-sections in our study can be explained by the fact that ours is a maternity hospital that provides care to high-risk patients, who require obstetric surgery more often.

Regarding the type of maternal intrapartum prophylaxis, ampicillin was used in most cases (93.5%). Penicillin, considered as the drug of first choice, was not used because it was not available at the hospital. According to Money, 2004, ampicillin is the option when penicillin is not available. Cefazolin is an alternative for patients allergic to penicillin without a history of anaphylaxis. Therefore, all patients were managed adequately[11].

The analysis of intrapartum obstetric management indicated that most colonized pregnant women received correct intrapartum prophylaxis (61.2%). However, most (57.5%) of the mothers given inadequate management were cases in which they received antibiotics within less than four hours of delivery. Some pregnant women (16.5%) were not prescribed antibiotics or were prescribed the wrong drug. A similar study by Costa et al. evaluated management practices in the same hospital between 2002 and 2006 and found a lower proportion of appropriate maternal management (43.2%) compared to the present study[3, 13].

All newborns with symptoms progressed well and were given adequate antibiotic therapy in accordance with the 2010 CDC guidelines. According to the American Academy of Pediatrics, ampicillin associated with an aminoglycoside is the treatment of choice for newborns with early GBS sepsis, a regimen prescribed at the institution where the study was conducted[4].

Most newborns (93.5%) were given adequate management based on the approach prescribed to their mothers, against 71% in the study by Costa et al. The performance of the neonatology team at implementing the guidelines also improved[3,13].

An analysis of intrapartum maternal management versus clinical progression of newborns found that attempts were made to improve the chances of newborns with potentially unfavorable outcomes, since 57.75% of adequately managed newborns had mothers administered inadequate obstetric management. In the present study, none of the newborns had proven sepsis, nor were there any deaths by GBS. Compared with the results of Costa et al., in which cases of sepsis and death by GBS were reported, there has been an improvement in the newborn outcomes[3,13].

Since this is a retrospective study based on the review of medical records, the information discussed herein rely heavily on the notes made by medical teams, which may be biased, incomplete, or incorrect. There were also cases in which we were unable not find the medical records of mothers and/or newborns, which contributed to losses in the study. Not all mothers colonized with GBS delivered their babies at our hospital, since many lived far from it.

The hospital at which the study was carried out is a tertiary referral center that provides care to high-risk mothers and newborns and children with malformations, which contributed to sample loss, since these children were excluded from the study in order to avoid confounding bias.

The hospital's obstetrics and neonatal care teams follow the 2010 CDC guidelines. However, there are gaps in the implementation of the guidelines, and the reasons behind the failure to comply with the guidelines must be analyzed.

It is important to point out that adherence to guidelines may be hindered for several reasons. First, it is necessary that everyone involved in the care of pregnant women and newborns has easy access to the guidelines and is properly trained. Lack of knowledge of the steps to follow or even of the existence of guidelines can cause it not to be implemented correctly. Thus, training and introducing the team to the steps they need to follow is essential for the success the guidelines.

Other limitations that can lead to failure in patient management include emergency situations and the lack of materials for the correct implementation of the guidelines. Items such as blood culture tubes and antibiotics must be available, while care teams must be engaged in the effort to deliver the best care to their patients. Performance must also be periodically reviewed in order to encourage the team to strive for better outcomes and address potential mistakes.

Although few studies have been carried out in Brazil on this subject and there are no standardized guidelines in the country, this is a relevant topic in Brazilian public health. The present study showed that performance has improved since the study by Costa et al. conducted between 2002 and 2006. [3,13] However, improvements are still needed in perinatal care and adherence to the CDC guidelines by hospital staff. Efforts are needed to disseminate the correct approaches to be adopted by obstetricians and neonatologists, in order to prevent early neonatal disease by GBS.

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