

Risk factors for early neonatal sepsis: retrospective Cohort in the Brazilian Amazon

Fatores de risco para sepse neonatal precoce: coorte retrospectiva na Amazonia brasileira

Factores de riesgo de sepsis neonatal temprana: cohorte retrospectivo em la Amazonía brasileña

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Abstract

Objective: to analyze risk factors for neonatal sepsis in a capital of the Brazilian Amazon region. **Methods:** Retrospective cohort of 411 mothers and their newborns assisted at the municipal maternity hospital from December 2019 to February 2020. Sociodemographic information, history of prenatal care, childbirth type and characteristics of the newborn were collected from the medical records of the binomial mother-child. To estimate the gross and adjusted Relative Risk and 95% confidence intervals, Poisson Robust Regression using Stata®, version 16.0 was used. **Result:** The incidence of sepsis was 75.42 per 1,000 live births. The risk factors for neonatal sepsis were previous infectious disease (RR: 2.40; 95% CI: 1.21; 4.76), APGAR score less than seven in the first minute (RR: 2.96; 95% CI: 1.17; 7.47) and low birth weight (RR: 5.60 CI; 95%: 1.69; 18.50). **Conclusion:** The identification of predictors for the outcome and early monitoring of pregnant women in prenatal care are important actions to minimize the occurrence of neonatal sepsis. For future studies, it is suggested research in the scope of primary health care and maternity for the qualification of professionals working in the line of care for pregnant women and their families.

Keywords: Neonatal sepsis; Maternal Health Services; Primary Health Care.

Resumo

Objetivo: analisar fatores de risco para sepse neonatal em Porto Velho, Rondônia. **Métodos:** Coorte retrospectiva com 411 puérperas e seus recém-nascidos assistidas na maternidade municipal no período de dezembro de 2019 a fevereiro de 2020. As informações sociodemográficas, história do pré-natal, parto e características do recém-nascido foram coletadas dos prontuários do binômio mãe-filho. Para estimar o Risco Relativo bruto e ajustado e intervalos de confiança a 95% empregou-se Regressão de Poisson Robusta por meio do Stata®, versão 16.0. **Resultado:** A incidência de sepse foi de 75,42 por 1.000 nascidos vivos. Os fatores de risco para sepse neonatal foram doença infecciosa prévia (RR: 2,40; IC 95%: 1,21; 4,76), boletim de APGAR menor que sete no primeiro minuto (RR: 2,96; IC 95%: 1,17; 7,47) e baixo peso ao nascer (RR: 5,60 IC; 95%: 1,69; 18,50). **Conclusão:** A identificação de preditores para o desfecho e acompanhamento precoce da gestante na assistência pré-natal são ações importantes para minimizar a ocorrência de sepse neonatal. Para futuros estudo, sugere-se investigar a qualificação da assistência prestada na linha de cuidados à gestante e seus familiares na atenção primária e na maternidade.

Palavras-chave: Sepse neonatal; Serviços de Saúde Materna; Atenção Primária à Saúde.

Resumen

Objetivo: analizar los factores de riesgo de sepsis neonatal en Porto Velho, Rondônia. **Métodos:** Cohorte retrospectiva con 411 puérperas y sus recién nacidos atendidos en la maternidad municipal en el periodo de diciembre de 2019 a febrero de 2020. La información sociodemográfica, los antecedentes prenatales y las características del parto y del recién nacido se recogieron de las historias clínicas del binomio madre-hijo. Para estimar el riesgo relativo bruto y ajustado y los intervalos de confianza del 95%, se utilizó la regresión de Poisson robusta con Stata®, versión 16.0. **Resultados:** La incidencia de sepsis fue de 75,42 por cada 1.000 nacidos vivos. Los factores de riesgo de sepsis neonatal fueron la enfermedad infecciosa previa (RR: 2,40; IC 95%: 1,21; 4,76), la puntuación de APGAR inferior a siete en el primer minuto (RR: 2,96; IC 95%: 1,17; 7,47) y el bajo peso al nacer (RR: 5,60 IC; 95%: 1,69; 18,50). **Conclusión:** La identificación de los depredadores del desfase y el acompañamiento precoz de la gestante en la asistencia prenatal son acciones importantes para minimizar la ocurrencia de septicemia neonatal. Para futuros estudios, se sugiere investigar la calificación de la asistencia prestada en la línea de atención a las mujeres embarazadas y sus familias en la atención primaria y en el hospital de maternidad.

Palabras clave: Sepsis neonatal; Servicios de salud materna; Atención primaria de salud.

1. Introduction

In 2019, in developing countries, 47% of infant deaths were newborns. About 30% of deaths occurred in the first 24 hours of life, resulting from complications of childbirth, congenital diseases and bacterial infections (WHO, 2020). In Brazil, in 2017 alone, 60% of infant mortality occurred in the neonatal period, with neonatal sepsis being one of the main causes of death (ANVISA, 2017).

Neonatal sepsis is the term used to designate systemic and invasive infection of bacterial, viral or fungal origin, with hemodynamic changes and other clinical manifestations (Shanes et al., 2017). This infection increases the risk of morbidity and mortality in the first 27 days of life (Teixeira, et al., 2019). Neonatal sepsis can be classified as early neonatal sepsis, between birth up to 48 or 72 hours of life, or late, between 72 hours and seven days of life, and may be asymptomatic or symptomatic (Shanes et al., 2017).

The clinical signs of early neonatal sepsis may be multiple and nonspecific, but the most common are thermal instability, respiratory dysfunction, apnea, jaundice, decreased spontaneous activity, absence of vigorous sucking, bradycardia, vomiting, diarrhea, abdominal distension, neonatal sepsis, convulsions, fontanel bulging, among others (Procianoy & Silveira, 2020). Diagnosis may be clinical, based on risk factors presented by the mother or newborn, or based on the results of culture and laboratory tests (Procianoy & Silveira, 2020).

Premature rupture of membranes, maternal chorioamnionitis, preterm delivery and Group B Streptococcus colonization are predictors of neonatal sepsis (Procianoy & Silveira, 2020). It is estimated that four out of 10 neonates with sepsis will acquire severe permanent damage, neuropsychomotor delay or die (Teixeira, et al., 2019). It is known that adequate care for women during pregnancy is the most efficient way to control maternal and child morbidity and mortality, through quality prenatal care capable of preventing undesirable outcomes, such as neonatal deaths (Gaiva et al., 2015).

Despite the advances made in Brazil to reduce maternal and child mortality in the northern region of the country, socioeconomic challenges and limited access to health services persist, which cause this region to continue to present a less favorable scenario regarding follow-up to pregnant women when compared to other states with better socioeconomic conditions (Pinheiro, et al., 2007; Moreira, et al., 2014). The early identification of risk factors may be useful for assertive actions to combat the worst neonatal outcomes due to sepsis. For this reason, the results of this research can contribute to the decision-making of health professionals and managers working in a capital of the Brazilian Amazon region or in places with similar characteristics. The study aims to analyze the risk factors for early neonatal sepsis and its incidence in a public maternity hospital in Porto Velho, Rondônia, considering the actions performed in primary health care.

2. Methodology

A retrospective cohort study conducted in the municipality of Porto Velho, capital of the state Rondônia, a region of the Brazilian Amazon, with 539,354 inhabitants, Brazilian Amazon region (Brasil, 2021). The study was conducted in the only municipal maternity hospital that assists pregnant women at usual risk. The maternity hospital performed, in 2019, 308 deliveries/month on average, approximately 70% vaginal delivery, and, as to the physical structure, there were 40 beds of joint accommodation, 11 of gynecology and 6 for intermediate care (MMME, 2019).

The population was composed of puerperal women over 12 years of age and their newborns, residents of the municipality, who were hospitalized from December 2019 to February 2020. The sample was calculated considering a confidence level of 95%, study power of 80%, proportion of one exposed for one not exposed, the main exposure variable was the number of consultations (< of six consultations) (Goulart, et al., 2006). After a pilot study with 100 participants, a 45% frequency and 1.31 risk were found for the non-exposure group, with the minimum sample estimated to be, including 10% for losses, 420 participants. Puerperal women with deliveries by vacuum extractor, forceps, with twin-newborns or with congenital malformations were excluded.

Data collection included records of the puerperal patient's medical records, notes from the multidisciplinary team, laboratory tests and the declaration of live birth. The dependent variable was early neonatal sepsis, defined as an infection that occurred between birth and 72 hours of life, being asymptomatic or symptomatic (Shanes, Sánchez & Stoll, 2017) and complying with the clinical and laboratory criteria of the maternity protocol. Early neonatal sepsis was confirmed in the presence of respiratory disorders, hemodynamic instability, poor general condition, food intolerance and altered vital signs. Laboratory tests, such as blood count, blood culture, PCR and cerebrospinal fluid research, were performed to define the diagnosis according to the recommendation of the studied maternity protocol.

The independent variables were organized as follows:

- Sociodemographic characteristics: age (< 20 years, 20 to 35 years or >35 years); maternal race/color (white or other); maternal education (> 9 or ≤ 9 years of schooling); marital bond (with or without a partner); place of residence (capital urban area, capital rural area and others); occupation (with or without remuneration).
- Gestational history: primiparous (yes or no); number of prenatal consultations (6 < or ≥ 6 consultations) (Brazil, 2013); some episode of UTI (yes or no); infectious diseases (tuberculosis, toxoplasmosis, viral hepatitis, cytomegalovirus, human immunodeficiency virus infection, herpes, syphilis, rubella and/or zika virus infection) (Procianoy & Silveira, 2020) (yes or no); antibiotic use in prenatal care (yes or no).
- Delivery information: gestational age of 37 < (yes or no) (Shanes, Sánchez & Stoll, 2017); Type of delivery (vaginal or cesarean); Signs of chorioamnionitis - at least one sign of fetid fluid, intrapartum fever, pain in the cervix, and softened uterus, haematological alteration (Procianoy & Silveira, 2020) (yes or no); premature rupture of membrane (yes or no); premature rupture of membrane time (< 18 or ≥ 18 hours) (Procianoy & Silveira, 2020); antibiotics in the maternity ward (yes or no).
- Information about NB: gender (female or male); weight < 2,500 grams (yes or no) (Puopolo, Benitz, Zaoutis, 2018); APGAR score ≥ 7 (yes or no) (Shanes, Sánchez & Stoll, 2017).

The data were presented in the form of absolute and relative frequencies for categorical data. Measures of central tendency (mean, median, standard deviation - SD) were used for numerical variables. Pearson's chi-square tests (χ^2) and Fisher's exact test were performed in the bivariate analysis. After bivariate analysis, the covariates were tested for the presence of multicollinearity, represented by correlations greater than 0.80 (Hamilton, 2006). All variables with a significance level of 20% or epidemiological relevance were considered as adjustment variables and submitted to multiple analysis (Paes, 2010).

The multiple analysis performed was Poisson Robust Regression to estimate relative risks (RR) and 95% confidence intervals (95% CI) using the stepwise forward selection strategy. In the saturated model, variables were maintained with results of $p < 0.05$, or that adjusted the measure of association by at least 10%, with relevance to the outcome in question or that improved the quality of the final model. The Akaike Information Criterion and the Bayesian Information Criterion of Schwarz were applied to verify the quality of adjustment of the final model. The statistical analysis was performed with the help of the statistical program Stata® version 16.0 (College Station, Texas, USA).

The present study was approved by the Research Ethics Committee of the Federal University of Rondônia - CAAE 20070719.5.0000.5300.

3. Results

The incidence of neonatal sepsis was 75.42 per 1,000 live births (95% CI: 51.82; 105.35). The mean maternal age was 25.19 years (SD: 5.78; minimum of 13 and maximum of 42 years) with 76.64% between 20 and 35 years.

Most of the participants lived in urban areas, had more than eight years of schooling, more than half worked without pay, the minority self-declared white. In relation to early neonatal sepsis, none of the sociodemographic variables was associated (Table 1).

Most puerperal women were multigravida, had prenatal care with an average of 7.28 consultations (SD: 2.49; minimum 1 and maximum of 14) and just over half had more than six consultations. Regarding urinary infection, 66.67% had at least one episode during pregnancy, 19.46% had an infectious disease and 69.23% used antibiotics.

Almost all newborns were born at term, at around 39.24 weeks (minimum of 30 and maximum of 40 weeks; SD: 1.27). The predominant delivery route was vaginal and in there was amniotic sac rupture in almost half of the cases. In 40.39% of the pregnant women, antibiotics were used in the prepartum.

Almost half of the newborns were male, with weight appropriate for gestational age (mean: 3,339 grams; SD: 482.15; 485 and maximum 4,660) and APGAR in the first minute above seven.

In the crude analysis, the presence of infectious disease during pregnancy increased the risk of NS by 2.61 times (95% CI: 1.34; 5.09) when compared to the group of mothers who did not present infectious disease, and no association of early neonatal sepsis with the other variables was identified (Table 1).

In the adjusted analysis, the presence of infectious diseases during pregnancy remained a risk factor for early neonatal sepsis (RR: 2.40; CI 95%: 1.21; 4.76), low birth weight resulted in 5.60 times more risk of being born with NS (95% CI: 1.69; 18.50) and the APGAR report below seven points at the end of the first minute, increased by 2.96 times the risk of newborns developing early neonatal sepsis (95% CI: 1.17; 7.47; Table 2). Cesarean delivery was a protective factor (RR: 0.44; IC95%: 0.21; 0.92) for the outcome.

The Statistical Test of Akaike and the Schwarz Bayesian Criterion (BIC) showed that there was improvement between the quality of the null and saturated model.

Table 1 - Sociodemographic characteristics, gestational history, birth and newborn information, Porto Velho, Rondônia, Brazil, 2020 (n = 411).

Variable	NB without sepsis N= 380 n (%)	NB with sepsis N= 31 n (%)	P-value	RR (CI95%)* **
Maternal age			0,19**	
20 to 35 years	292 (92,70)	23 (7,30)		1
< 20 years old	65 (89,04)	8 (10,96)		1,61 (0,76 - 3,41)
> 35 years old	23 (100,00)	-		
Race/Maternal Color *			0,44**	
White	25 (89,29)	03 (10,71)		1
Other	299 (93,15)	22 (6,85)		0,64 (0,21 - 1,96)
Maternal education			0,58	
> 9 years of study	263 (92,93)	20 (7,07)		1
≤ 9 years of study	117 (91,41)	11 (8,59)		1,21 (0,61 - 2,43)
Marital bonding			0,34	
With mate	286 (93,16)	21 (6,84)		1
No mate	94 (90,38)	10 (9,62)		1,41 (0,69 - 2,85)
Place of residence			0,25**	
Capital urban area	333 (91,74)	30 (8,26)		1
Capital countryside	23 (91,74)	01 (4,17)		0,25 (0,36 - 1,74)
Other	24 (100,00)	-		
Occupation			0,83	
Paid	117 (92,86)	09 (7,14)		1
No pay	263 (92,28)	22 (7,72)		1,08 (0,52 - 2,25)
Gestational history				
Primiparous			0,86	
No	275 (92,59)	22 (7,41)		1
Yes	105 (92,11)	09 (7,89)		0,94 (0,45 - 1,95)
Number of prenatal consultations*			0,41	
≥ 6 queries	234 (93,23)	17 (6,77)		1
< 6 queries	141 (90,97)	14 (9,03)		1,32 (0,68 - 2,57)
Some episode of ITU			0,18	
No	130 (94,89)	07 (5,11)		1
Yes	250 (91,24)	24 (8,76)		1,71 (0,77 - 3,82)
Infectious Disease			<0,01	
No	312 (94,26)	19 (5,74)		1
Yes	68 (85,00)	12 (15,00)		2,61 (1,34 - 5,09)
Antibiotic use in prenatal care*			0,08**	
No	115 (95,83)	05 (4,17)		1
Yes	245 (90,74)	25 (9,26)		2,22 (0,89 - 5,56)
Childbirth information				
Prematurity			0,38**	
No	375 (92,59)	30 (7,41)		1
Yes	05 (92,1)	01 (16,67)		2,25 (0,38 - 13,44)
Type of delivery			0,11	
Vaginal	228 (90,84)	23 (9,16)		1
Cesária	152 (95,00)	08 (5,00)		0,55 (0,25 - 1,17)
Signs of corioamnionitis			0,25	
No	331 (93,77)	22 (6,23)		1
Yes	49 (84,48)	09 (15,52)		1,48 (0,75 - 2,87)
Rota bag			0,11	
No	226 (94,17)	14 (5,83)		1
Yes	154 (90,06)	17 (9,94)		1,70 (0,87 - 3,32)
Bag time route n= 171			0,52**	
< 18 hours	135 (90,60)	14 (9,40)		1
≥ 18 hours	19 (86,36)	03 (13,64)		1,45 (0,46 - 4,58)
Used antibiotics in maternity			0,57	
Yes	152 (91,57)	14 (8,43)		1
No	228 (93,06)	17 (6,94)		1,21 (0,62 - 2,37)
Information about the newborn				
Sex			0,64	
Female	188 (93,07)	14 (6,93)		1
Male	192 (91,87)	17 (8,13)		1,17 (0,60 - 2,29)
Low birth weight (> 2,500 grams)			0,17**	
No	371 (92,75)	29 (7,25)		1
Yes	09 (81,82)	02 (18,18)		2,51 (0,70 - 8,99)
Good vitality when born (APGAR score ≥ 7)*			0,13**	
Yes	369 (92,71)	29 (7,29)		1
No	08 (80,00)	02 (20,00)		2,74 (0,78 - 9,70)

Legend: * Missing Data; ** Fisher's Exact Test was used; ***RR: relative risk, CI95%: 95% confidence interval. Source: Authors.

Table 2 - Adjusted relative risk in relation to neonatal sepsis, Mãe Esperança Municipal Maternity, Porto Velho, Rondônia, Brazil, 2020 (n = 411)

Variable	RR (IC95%)*
Residence	
Interior or other state	0,29 (0,04 - 2,08)
ITU in pregnancy	
Yes	1,18 (0,44 - 3,19)
Infectious diseases in pregnancy	
Yes	2,40 (1,21 - 4,76)
Antibiotic use in pregnancy	
Yes	1,93 (0,63 - 5,91)
Signs of corioamnionitis	
Yes	1,31 (0,69 - 2,50)
Rota bag	
Yes	1,33 (0,68 - 2,59)
Type of delivery	
Cesarean	0,44 (0,21 - 0,93)
Sex	
Male	1,20 (0,64 - 2,27)
Low birth weight ($\leq 2,500$ grams)	
Yes	5,60 (1,69 - 18,50)
Good vitality at birth (APGAR ≥ 7)	
No	2,96 (1,17 - 7,47)

* RR: relative risk, CI95%: 95% confidence interval. Source: Authors.

4. Discussion

The incidence of PNS in the maternity ward of Porto Velho was 75.42 per 1,000 live births and the risk factors for sepsis were the presence of infectious diseases during pregnancy, low birth weight and presenting an APGAR report lower than seven points at the end of the first minute. Cesarean delivery was a protective factor for the outcome.

In this study, the incidence of early neonatal sepsis was higher than a study conducted in the state of Amazonas, which identified an incidence of 53 cases /1,000 live births in 302 puerperal women and their newborns in a high-risk public maternity (Pinheiro, et al., 2007). On the other hand, the incidence of early neonatal sepsis was lower than the results identified in a study in the state of Paraná, when evaluating 520 newborns hospitalized in a Neonatal Intensive Care Unit from 2014 to 2016, whose incidence was 140.38 cases per 1,000 live births (De Souza, 2020).

Although the study comes from the southern region of the country, the high incidence of early neonatal sepsis can be explained as it is a study restricted to a reference hospital for high-risk pregnant women, therefore, they had factors known to be associated with early neonatal sepsis independent of the region.

In the present study, no association was identified between sociodemographic variables and neonatal sepsis. However, other studies indicate that race/skin color, schooling and income are determining factors for the use of health services, presence of morbidity and infant mortality (Sanders, et al., 2017; Pacheco, et al., 2018). In the gestational history, the association of the presence of early neonatal sepsis with a history of infectious diseases such as toxoplasmosis, viral hepatitis, cytomegalovirus, Human Immunodeficiency Virus, herpes and syphilis was observed. Newborns with congenital syphilis, for example, who also have early neonatal sepsis, tend to evolve with unfavorable prognoses (Liu, et al., 2019). In addition, it is known that the presence of infectious diseases during pregnancy is related to low access of users to prenatal care or the low quality of the care provided (Da Costa, et al., 2017; Favero, et al., 2019; Alves, et al., 2020).

The absence of an association between urinary tract infection and early neonatal sepsis may be related to the use of antibiotics during pregnancy, since many puerperal women were treated with this drug in prenatal care. However, it is a relevant finding, since 20% of pregnancies complicated by urinary tract infections are preventable through educational actions, prophylactic measures, early diagnosis and treatment (Pompermaier et al., 2020; De Souza, 2020). A systematic review of

36,016 pediatric records showed that newborns of mothers with a history of urinary tract infection during pregnancy had a 3.55 times higher risk of developing neonatal sepsis compared to babies of mothers who did not have prenatal urinary tract infection (Bayih, et al., 2021).

Adequate prenatal follow-up is important for the early identification of risk factors for neonatal sepsis. The number of consultations and the adequacy of clinical actions in prenatal care should be considered. Maternal-child health care is one of the main prevention strategies recommended in the sphere of Primary Health Care, although a low adequacy of care for pregnant women prevails when compared to recommended policies (Tomasi, et al., 2017; Genovesi, et al., 2020; Leal, et al., 2020). Weaknesses, such as incomplete clinical evaluation, lack of interprofessionality approaches, late onset and absence of person-centered health education, make care fragmented and flawed (Silva, et al., 2019; Leal, et al., 2020). Ineffective prenatal follow-up increases the chances of early neonatal sepsis occurrence by about 10 times (Alves, et al., 2018).

Regarding the variables related to delivery, contrary to what was expected, cesarean delivery was a protective factor for newborns, similar to another study on neonatal mortality (Sanders, et al., 2017). One possible explanation is the presence of microorganisms in the vaginal canal, such as Group B Streptococcus (Procianoy & Silveira, 2020). In the municipality where the study was conducted the collection of vaginal secretion for GBS investigation is not performed routinely, although there are recommendations that it is essential to investigate the presence of the same through culture of vaginal/rectal secretion between 35th and 37th weeks of gestation and immediate treatment to avoid contamination of newborns in the vaginal canal during delivery (Martins, et al., 2017).

Regarding the characteristics of the newborn, there was an association between early neonatal sepsis and low birth weight and APGAR bulletin score lower than seven in the first minute of life, corroborating the findings of other studies on factors associated with the presence of early neonatal sepsis (Shanes, Sánchez & Stoll, 2017; Silva, et al., 2019; Martins, et al., 2017). Low birth weight is one of the main risk factors for the survival of newborns, as it increases the risk of mortality and early neonatal sepsis (Alves, et al., 2020; Alves, et al., 2018). Regarding the low vitality of the newborn, a research conducted in the South of the country, conducted between 2000 and 2013, found an association between the occurrence of hypoxia, asphyxia and history of resuscitation and neonatal sepsis (Alves, et al., 2018).

Among the weaknesses of this study, it is recorded that, because it is a retrospective study, it is dependent on adequate records made by the multidisciplinary team in the medical records and other documents of the puerperal and her newborn. Moreover, despite the collection of information in medical records or declaration of live birth being considered a good source of information, the absence of important information in some medical records was verified, such as the performance of prenatal exams, as well as their results, and the record of the beginning of prenatal follow-up. However, to minimize bias in the collection, a double-check method was used, that is, the collected data were checked by more than one collector.

5. Conclusion

As a conclusion to this study, it is noteworthy that the presence of infectious diseases during pregnancy, low birth weight and APGAR report lower than seven points at the end of the first minute were risk factors for early neonatal sepsis and cesarean delivery was a protective factor. The infections identified are preventable and treatable for a low cost, so sepsis can be avoided in exposed neonates in a timely manner. For future studies, it is suggested research in the scope of primary health care and maternity for the qualification of professionals working in the line of care for pregnant women and their families. To investigate how the available structure and the work process experienced by professionals has influenced the quality of prenatal care provided to users and their families.

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