Neonatal near miss in the intensive care unit

Near miss neonatal em unidade de terapia intensiva
Near miss neonatal en una unidad de cuidados intensivos

Maria Rita Guimarães Maia [I]
ORCID: 0000-0002-2496-1960

Rosângela Aparecida Pimenta Ferrari [II]
ORCID: 0000-0003-0157-7461

Alexandrina Aparecida Maciel Cardelli [II]
ORCID: 0000-0002-0222-8821

Ieda Harumi Higarashi [III]
ORCID: 0000-0002-4205-6841

Maria Dalva de Barros Carvalho [III]
ORCID: 0000-0002-1377-3331

Sandra Marisa Pelloso [III]
ORCID: 0000-0001-8455-6839

[I] *Universidade do Oeste Paulista. Presidente Prudente, São Paulo, Brazil.*
[II] *Universidade Estadual de Londrina. Londrina, Paraná, Brazil.*
[III] *Universidade Estadual de Maringá. Maringá, Paraná, Brazil.*

Corresponding author:
Maria Rita Guimarães Maia
E-mail: ritaisa@outlook.com.br

ABSTRACT
Objective: To analyze near miss cases among newborns hospitalized in the Intensive Care Unit. **Methods:** An observational, cross-sectional, retrospective study using the STROBE guideline. Data were collected from 1,101 records of live births (newborns). Statistical analysis used the Epi-Info program 3.3.2 and Chi-square and Fisher's exact tests. **Results:** A total of 162 newborns were hospitalized, of which 63 had at least one criterion of near miss. The variables that remained associated with neonatal near miss were weight <1.750 g, gestational age <33 weeks and Apgar at 5 minutes <7, pragmatic criteria to identify cases of neonatal near miss morbidity. **Conclusion:** Prematurity and low birth weight were the factors that contributed most to the near miss outcome among newborns hospitalized in intensive care, a rate two and a half times higher than the number of deaths, according to scientific evidence.
Descriptors: Morbidity; Neonatal mortality; Near miss; Nursing; Neonatal Intensive Care Units.

RESUMO
Objetivo: Analisar casos de *near miss* entre recém-nascidos internados em Unidade de Terapia Intensiva. **Métodos:** Estudo observacional, transversal, retrospectivo, que utilizou a diretriz STROBE. Os dados foram coletados em 1.101 prontuários de recém-nascidos vivos. A análise estatística utilizou o programa Epi-Info 3.3.2 e testes Qui-quadrado e Exato de Fisher. **Resultados:** Foram internados 162 recém-nascidos. Destes, 63 apresentaram pelo menos um critério de *near miss*. As variáveis que permaneceram associadas ao *near miss* neonatal foram peso <1.750g, idade gestacional <33 semanas e Apgar no 5° minuto <7, marcadores pragmáticos para identificar casos de morbidade neonatal *near miss*. **Conclusão:** Prematuridade e baixo peso foram os fatores que mais contribuíram para o desfecho *near miss* entre os recém-nascidos internados na Terapia Intensiva, taxa duas vezes e meia superior ao número de óbitos, de acordo com evidências científicas.
Descritores: Morbidade; Mortalidade Neonatal; *Near Miss*; Enfermagem; Unidades de Terapia Intensiva Neonatal.

RESUMEN
Objetivo: Analizar los casos de near miss en recién nacidos internados en la Unidad de Cuidados Intensivos. **Métodos:** Estudio observacional, transversal, retrospectivo que utilizó la declaración STROBE. Los datos fueron recolectados en 1.101 prontuarios de recién nacidos vivos. El análisis estadístico utilizó el programa Epi-Info 3.3.2 y las pruebas de Chi-cuadrado y Exacta de Fisher. **Resultados:** Fueron hospitalizados 162 recién nacidos, 63 de los cuales tenían al menos un criterio de near miss. Las variables que permanecieron asociadas al near miss neonatal fueron peso <1.750g, edad gestacional <33 semanas y Apgar a los 5 minutos <7, marcadores pragmáticos para identificar casos de morbilidad neonatal near miss. **Conclusión:** La prematuridad y el bajo peso fueron los factores que más contribuyeron al resultado near miss de los recién nacidos en Cuidados Intensivos, tasa dos veces y media superior al número de muertes, de acuerdo con evidencias científicas.
Descriptores: Morbilidad; Mortalidad Neonatal; Near Miss; Enfermería; Unidades de Terapia Intensiva Neonatal.

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INTRODUCTION

The concept of near miss has been used in epidemiology and medicine since the 1970s to characterize the quality of care for survivors who are victims of serious morbidity conditions that could lead them to death[1].

In health care, this term is used in situations of near error or incident identified in time to be avoided or minimized. In neonatology and obstetrics, it is defined as an event in which the newborn on the verge of death survives complications during pregnancy, childbirth or in the first 28 days of life[1-4].

The conception and interpretation of criteria for defining neonatal near miss cases demonstrates the important achievements in the management and evaluation of the care of critical newborns at risk for death. Even with a different outcome, a case of near miss should be as similar as possible to a case of death, as the newborn had serious complications, almost died, but survived the neonatal period[3-4].

These criteria must be simple, clear and applicable to different realities, institutions and health teams. As with the maternal near miss approach, they are useful tools for assessment of care, improvement and qualification of newborn healthcare, especially in intensive care units. Neonatal near miss cases represent a number from three (3) to six (6) times higher in relation to deaths in these contexts[3,5].

The use of reliable and easy to apply tools is essential in these services. They should portray the reality of health units and provide information to support the diagnoses and quality of care planning[3].

In some studies, management and/or pragmatic criteria are used to identify cases of near miss. In the "Global Survey on Maternal and Perinatal Health" study (WHOGS), pragmatic criteria related to prematurity were used, such as low weight <1.750g, gestational age less than 33 weeks and the Apgar score at 5 minutes of life less than 7. These criteria are generally retrospective and derived from vital statistics often collected from medical records and other documents[3-4].

Even with the wide use of pragmatic and management criteria associated with preventable factors worldwide, in their neonatal near miss review in 2014, the Pan American Health Organization (PAHO), the World Health Organization (WHO) and the Ministry of Health (MS) guidance was towards inclusion of such criteria, but there was a lack of studies evaluating them. A systematic review study in electronic databases of PubMed, Scielo and EMBASE in 2015, resulted in four selected articles on pragmatic and management criteria, in addition to the rates of occurrence of near miss compared to mortality rates with characteristics of other multicenter studies[4,6-7]. Thus, this study is justified by the scarcity of works on this topic and by the need to investigate and apply pragmatic criteria in hospital institutions in the inlands of the State of São Paulo.

The aim of this study was to analyze the cases of near miss among newborns admitted to the Intensive Care Unit according to one of the following variables: birth weight <1.750g, Apgar at 5 minutes <7 and gestational age (GA) <33 weeks. These criteria are in consensus with the definition of near miss by the WHO[3]. Although they are not adopted in the hospital under study, their development and validation may facilitate the identification of cases of near miss and be a tool for the assessment of quality and guidance of care to newborns, with direct interference in neonatal morbidity and mortality rates at local and state levels.

OBJECTIVE

To analyze the cases of near miss among newborns admitted to the Intensive Care Unit, according to one of the following variables: birth weight <1.750g, Apgar score at 5 minutes <7 and gestational age (GA) <33 weeks. Such criteria are in consensus with the definition of near miss by the World Health Organization.

METHODS

Ethical aspects

Study approved by the Ethics Committee/CEP system/CONEP/Plataforma Brasil/Ministry of Health. All the requirements of the Guidelines and Regulatory Norms for Research Involving Humans of the National Health Council were respected.

Study design, period and location

This is an observational, cross-sectional and retrospective study based on documents, in which the STROBE guideline was used. Medical records of live newborns of 1,130 women who gave birth in a teaching hospital in Presidente Prudente (state of São Paulo, Brazil) were analyzed.

Two hospitals that offer care for the National Health System (Brazilian SUS) users are part of the maternal and child care network in the city, namely an outpatient clinic of medical specialties (Portuguese acronym: AME) and an outpatient clinic of the Regional Hospital (Portuguese acronym: HR), which is responsible for monitoring pregnant women at risk referred by primary care[8].

The hospital has a Neonatal Intensive Care Unit (NICU), the scenario of the present study. It has 20 beds, of which ten for intensive care and ten for intermediate care. The team working directly in care is composed of six nurses, 29 nursing technicians and three doctors.

The choice of the location for the development of this study is related to its hypothesis, the profile of service users, the fact that this is a single service unit and reference of this size in the city and western region of the state of São Paulo.

A script arranged in three distinct phases was followed for data collection. The first phase was the definition of medical records of mothers and newborns born in the period between January 1, 2014 and December 31, 2014, based on the records of the Book of the Obstetric Center and the NICU.

In the second phase, medical records were analyzed in order to identify information that presented the inclusion criteria of the study. Subsequently, data were collected between May 2015 and August of the same year with use of an instrument developed by the researcher (Appendix A).

Population or sample; inclusion and exclusion criteria

The total of 1,130 medical records of newborns were selected. The inclusion criteria were related to medical records of live

newborns generated in the obstetric service of the institution containing the necessary information for preparing the database. The total of 29 records were excluded because they did not contain all the information necessary for the analysis of variables. The sample included 1,101 records of newborns (Figure 1).
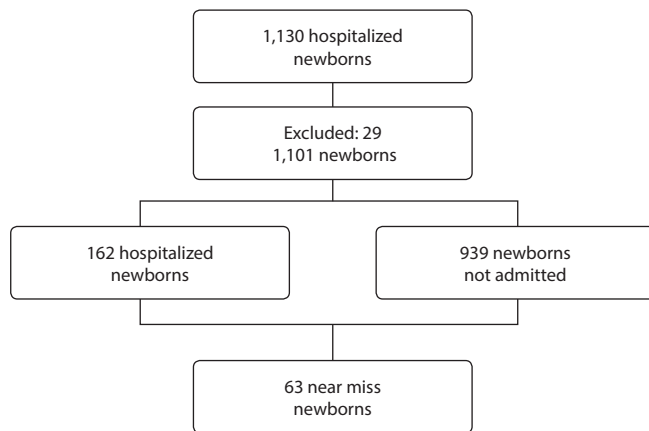

Figure 1 - Flowchart of analysis of the neonatal near miss study

Study protocol

Data were collected from medical records of newborns using instruments made by the researchers. They contained data related to the following characteristics: identification, place of hospitalization, weight, gestational age, diagnoses (medical and nursing), dates (birth, data collection), anthropometric measurements and Apgar score, vaccines, specific tests, malformations, complications and interventions.

The dependent variable was the occurrence of near miss and the independent variables were gestational age (less than 33 weeks), Apgar score (less than 7 at 5 minutes) and weight (less than 1.750 g), according to the WHOGS study [3].

Analysis of results and statistics

The collected data were entered in the Excel program, (*Statística 7.1* software). Crude analysis was used through odds ratio (OR), X^2 test (p<0.05) in the Epi-Info 3.5.1 statistical program, as well as through the Fisher's exact test, when applicable.

The neonatal near miss rate (NNMR) was constructed using the formula: NNMR = number of NM cases x 1000/LB, where LB is related to live births (LB) in the institution.

RESULTS

The total of 1,130 medical records of newborns was selected at the Regional Hospital of Presidente Prudente (SP) between January and December 2014. Given the lack of records in the respective documents for the analysis of variables, 29 medical records were excluded from the study. Of the total number of newborns, 14.4% (162) were admitted to the NICU.

The occurrence of prematurity among newborns (gestational age <33 weeks), low Apgar score (Apgar at 5 minutes <7) and low birth weight (weight <1.750g) were statistically associated with NICU admission after application of the Chi-square and Fisher's exact tests.

The outcome of hospitalization in the NICU was higher for those with birth weight <1.750g (OR: 94.17; 95% CI: 36.87; 240.55; p-value <0.001); and born at <33 weeks of gestation (OR: 472.88; 95% CI: 64.76; 3452.97; p-value: <0.001). The Apgar score at 5 minutes was not a contributing factor for association with NICU admission (OR: 1.64; 95% CI: 0.88; 3.05; p-value =0.1637) (Table 1).

Table 1 - Frequency of pragmatic severity criteria among live newborns according to admission to the Intensive Care Unit, Presidente Prudente, São Paulo, Brazil, 2016*

Variable	ICU		OR* (95% CI)	p value
	Yes n	No n		
Weight				
< 1.750	54 (33.5%)	5 (0.5%)	94.17	**< 0.0001**
≥ 1.750	107 (66.5%)	933 (99.5%)	(36.87; 240.55)	
Apgar at 5 minutes				
< 7	14 (8.6%)	47 (5.5%)	1.64	0.1637
≥ 7	148 (91.4%)	815 (94.5%)	(0.88; 3.05)	
Gestational age				
< 33 weeks	54 (33.5%)	1 (0.1%)	472.88	**< 0.0001**
≥ 33 weeks	107 (66.5%)	937 (99.9%)	(64.76; 3452.97)	

Note: *OR: crude odds ratio; 95% confidence interval.

The analysis of the database using one of the three pragmatic criteria (WHOGS): weight <1.750 g, GA <33 weeks or Apgar at 5 min <7 allowed the identification of neonatal near miss cases among newborns admitted to the NICU. Therefore, all newborns who survived the 27 days of life hospitalized were classified as cases of neonatal near miss morbidity, totaling 63 cases.

The neonatal near miss rate was 55.75 per 1,000 live births, corresponding to almost three times the number of neonatal deaths, which was 24/1,000 LB in 2014.

Gestational age <33 weeks was identified in 85.7% of hospitalized newborns, and this was the factor that most contributed to the near miss rate. The second factor that most contributed was low birth weight, since 68.3% of newborns with severe neonatal morbidity had weight <1.750g, while Apgar <7 was identified in 22.2% of newborns diagnosed as near miss (Table 2).

Table 2 - Factors that contributed to neonatal near miss cases. Presidente Prudente, São Paulo, Brazil, 2016[†]

Variable	Near Miss		OR[†] (95% CI)	p value
	Yes n	No n		
Weight < 1.750				
Yes	43 (68.3%)	12 (12.1%)	15.79	**< 0.0001**
No	20 (31.7%)	87 (87.9%)	(6.98; 34.81)	
Apgar at 5 min < 7				
Yes	14 (22.2%)	1 (1.01%)	28	**< 0.0001**
No	49 (77.8%)	98 (98.98%)	(3.58; 219.15)	
Gestational age < 33 weeks				
Yes	54 (85.7%)	1 (1.01%)	588	**< 0.0001**
No	9 (14.3%)	98 (98.98%)	(72.54; 4766.09)	

Note: [†]OR: crude odds ratio; 95% CI: 95% confidence interval.

According to Table 2, the chance of a newborn weighing less than 1.750 g being a near miss case is 15 times greater than that of not being, even hospitalized in the ICU. Likewise, the chance of a newborn having an Apgar at 5 minutes less than 7 and being a

near miss case was 28 times greater than that of not being. The chance of being born before 33 weeks of gestation and being classified as near miss was 588 times greater than that of being admitted to the ICU but not being a near miss case.

DISCUSSION

The lack of studies on the occurrence of neonatal near miss cases in hospitals in the interior of the state of São Paulo using the pragmatic criteria established in consensus with PAHO/WHO directed the present study in the municipality of Presidente Prudente (SP).

In 2014, the 45th administrative region of the State of São Paulo, which has Presidente Prudente (SP) as headquarters, accounted for more than 9,000 live births, out of which 2,879 were in the municipality. Of this amount, the Regional Hospital (the present study setting) contributed with 39.2% of births (N: 1,130)[8].

The infant mortality rate in the region in the surveyed period (2014) was 12.1/1,000 LB. It decreased in 2015, with a rate of 11.43, below the rates in Brazil in years 2011 (14/1,000 LB) and 2015 (13.82/1,000 LB). As in the literature, the neonatal mortality rate has been decreasing over the years, although more slowly[8-9].

In Brazil, in 2011 and 2012, neonatal mortality rates were 11.1 and 10.6/1,000 live births, respectively, while in the state of São Paulo, it reached 7.9 neonatal deaths per 1,000 live births in 2012. Note that in 2014, the highest indicator was found in the region of Presidente Prudente, with rates of 10.4/1,000 live births[9-11].

From January to December 2014, the NICU of the Regional Hospital of Presidente Prudente registered 162 hospitalizations of newborns. Of these, 24 died in the neonatal period (children aged 0 to 27 days). The neonatal mortality rate was 21.2/1,000 LB, while the neonatal near miss morbidity rate was 55.75/1,000 LB, almost three times higher than the neonatal mortality rate. A similar result was found in the *Nascer no Brasil* survey ('Being born in Brazil', free translation), which presented a newborn near miss rate four times higher than the neonatal mortality rate[6].

The variables GA, weight and Apgar score were tested in association with the outcome of NICU admission. Later, in the presence of one or more variables, they were associated with the neonatal near miss outcome, which showed high sensitivity and specificity to predict neonatal mortality, since this indicator is considered an event that almost resulted in death[3-4,9].

In this study, the results of the analysis of gestational age and newborn weight are like those found in the literature. Gestational age related to prematurity was the most important risk factor found in associations with neonatal morbidity and mortality. It may cause immediate or late problems to the child, related to hypoxia, hyaline membrane syndrome, intracranial hemorrhages and infections, among other conditions, in addition to accounting for one million of neonatal deaths worldwide[12-14].

Very premature newborns (GA <33 weeks) were identified in 85.7% of newborns admitted to the NICU of the institution studied. Other studies point to a strong relationship between prematurity and neonatal mortality, and this is one of the criteria that characterizes near miss cases, especially if associated with low weight. Under these conditions, newborns are at higher risk for mortality, even when they were born with adequate Apgar and in the absence of asphyxia, as found in this study[12,15-17].

Premature birth is a multifactorial event. It can be the result of pathological processes such as premature activation of the maternal and fetal hypothalamic-pituitary-adrenal axis, also by infection or inflammation, by decidual hemorrhage or by pathological uterine distention. Its occurrence is also a result of erroneous calculation of GA, considered iatrogenic[16-17].

Risk factors for prematurity can be classified into biological, sociodemographic and care factors. Inherent risks to pregnant women and newborns conditions are added to biological factors, for example: previous diseases of the mother, use of alcohol and drugs, hypertension, diabetes, HIV or other infectious or sexually transmitted diseases, as well as low birth weight, Apgar score < 7 at 5 minutes and newborn malformations, among others[6].

The following are among sociodemographic risk factors: mother under 19 years old, illiterate, having the role of family "breadwinner" - usually due to the absence of a partner, having more than three children alive and at least one child who did not survive the first year of life. Other conditions include living in a vulnerable area, without adequate prenatal care (at least six consultations), in addition to the partner or the pregnant woman herself being a drug addict[6].

The following risk conditions were related to care: type of delivery, adequacy of care and number of prenatal consultations, place of birth and characteristics of the health institution where the childbirth took place in relation to lack or presence of trained human resources, nursery and neonatal intensive care unit with adequate infrastructure, in addition to more complex technological resources[6].

Contrary to some social and regional factors associated with pregnant women with lower purchasing power and educational level, in most developed countries, the number of premature births increases and determines the prevalence of low birth weight by the number of multiple births as a result of infertility treatments, especially in women aged over 35 years, who had cesarean sections and premature induction of labor[4,9].

Low birth weight was the second most important predictor of neonatal morbidity and contributed to cases of near miss. In a study conducted in Curitiba (state of Paraná) and metropolitan region to identify the risk factors for neonatal mortality among live births in 2001 and 2011, was identified an association of low weight with the outcome of neonatal death, the same criterion for near miss[3-4,9].

Low weight is considered the most significant risk factor for neonatal morbidity and mortality. It contributes with 28 to 36 times to the highest risk of death compared to live births weighing >2.500g. A newborn weighing <1.750g, a pragmatic criteria for near miss, may result from precarious sociodemographic conditions and maternal and neonatal care[12,14,18].

Apgar scores at 1 and 5 minutes of life should not be used as the sole criteria for assessing the need for interventions, but rather to simultaneously accompany and monitor the result of maneuvers performed. Apgar scores from 7 to 10 generally mean good conditions of vitality, and when this score is <7, it is a warning sign for the health team, which should also analyze weight and prematurity, together with asphyxia and malformations, among other conditions[13,17,19].

New knowledge started to direct the need for resuscitation maneuvers and the precision in diagnosis of neonatal asphyxia.

It is not recommended to wait for the Apgar score at 1 minute for such interventions, but rather that laboratory tests, such as the fetal blood pH, make up the diagnosis of asphyxia with the need for immediate maneuvers. Nonetheless, the score at 1 minute can predict the prognosis of early or late neonatal mortality[17,20-24].

In this study, although Apgar scores at 5 minutes were not associated with NICU admission, they were significant for composing the neonatal near miss rate by identifying in low weight (<1.750 g) and gestational age (<33 wk), the main markers for the outcome. This result is contrary to the study conducted in the capital of São Paulo, which was aimed at assessing the influence of the Apgar score on neonatal mortality. The Apgar score of the studied population was found to be a good instrument for predicting the risk for death[17-18].

The health team must analyze weight, prematurity, asphyxia and malformations, among other conditions, in addition to maternal conditions such as the use of medications, although Apgar scores should also be considered warning signs[5,13,19].

The need for resuscitation maneuvers and the accuracy in the diagnosis of neonatal asphyxia should not be subordinated only to waiting for the Apgar evaluation at 1 minute. Other resources, such as laboratory tests, with attention to the fetal blood pH, should make up the diagnosis of asphyxia and severe morbidity with need for immediate interventions, because they can predict the prognosis of early or late neonatal mortality[21,-24].

The institution of measures aimed at improving the health of pregnant women and newborns requires regionalized networks of perinatal healthcare. For comprehensive care, it is essential to know the conditions of birth and mortality, as well as the indicators related to the type of childbirth (mainly cesarean sections), gestational age (with special attention to prematurity), mother's age (with emphasis on extremes of age), birth weight (low, very low or extremely low) and vitality of the newborn (Apgar score and identification of asphyxia at birth)[10].

Study limitations

The fact of using medical records as the only source of data collection in this study can be considered a limitation, since some information may not have been recorded and there was no access to pregnant women's card and other prenatal documents. However, the results allowed a better understanding of factors related to neonatal mortality and maternal socioeconomic status and may support other studies that broaden the discussion on failures in prenatal care and in hospital support for childbirth care.

Contributions to the field of nursing, health or public policy

This study allowed reflections on academic and professional practice, the commitment and social responsibility of nursing. Increasingly, nurses have assumed managerial functions at different levels and scenarios of health care thereby making the planning, control and evaluation necessary instruments for guiding their actions.

Thus, the diagnosis and knowledge of the health situation of the population under their care are essential for care planning. In this sense, this study may awaken the nursing team to the valorization and accountability for their actions. Once planning and decisions are guided by scientific evidence and based on investigation and reflection, they will culminate in preventive and care measures, especially to vulnerable groups.

It is known that factors related to neonatal mortality and maternal socioeconomic status originate mainly from failures in prenatal care and childbirth care with inadequate hospital support. These elements are considered preventable factors and need intervention by the three spheres of government and society for the modification of local, state and national realities.

CONCLUSION

Even with scientific and technological development regarding maternal and child health, mortality rates remain a challenge to be overcome. In the studied institution, the occurrence of prematurity and low birth weight were associated with higher rates of hospitalization in the NICU and the neonatal near miss outcome, which had a rate almost three times higher than that of mortality.

The near miss approach using one of the three pragmatic criteria - weight <1.750g, GA <33 weeks and Apgar score <7 at 5 minutes of life - proved to be a simple tool of easy application for the evaluation of perinatal healthcare. This characteristic of the application of the near miss concept does not depend on the level of development of the institution and is an important factor that suggests its implementation as a routine activity in the studied health service.

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